Azienda Sanitaria Locale PESCARA
U.O.C. INGEGNERIA CLINICA – HTA
Via Renato Paolini, 47 – 65126 PESCARA (PE)
Tel. 085.4253109 – ingegneriaclinica@asl.pe.it
Direttore: Dott. Ing. Vincenzo Lo Mele

Mod. 01/IC
Rev. 01 del 17/10/2024
"Verbale di Accettazione e Collaudo di Apparecchiatura Elettromedicale"

VERBALE DI COLLAUDO

ID COLLAUDO IC169/25 *DATA* 23/10/2025

RIF. PRATICA

PRESIDIO: PESCARA U.O. CHIRURGIA PEDIATRICA

N° DETERMINA/DELIBERA: 3593 HTA del 22/10/25 N° ORDINE 20-2025-140 del 14/10/25

Ditta Fornitrice : OLYMPUS ITALIA SRL Rif. DDT : 77174679 DEL 17/10/25

Note: _____

ID. APPARECCHIATURA/E E ACCESSORI/COMPONENTI

TIPOLOGIA	*MARCA*	*MODELLO*	*NUMERO DI SERIE*	*CODICE AEM*
VIDEOGASTROSCOPIO	OLYMPUS	GIF-1100 EVIS X1	2510118	E015922

Note: _____

CAUSALE ACQUISIZIONE: ☒ACQUISTO ☐SERVICE ☐NOLEGGIO ☐COMODATO ☐DONAZIONE ☐_____

Durata Periodo di Garanzia: 12 *mesi* Data Scadenza Garanzia : 22 / 10 / 2026

Durata ☐Service ☐Noleggio ☐ Comodato: [redacted] *mesi* Data Scadenza : [redacted]

Importo complessivo della fornitura IVA INCLUSA: € 33.962,41 (corrispondente all' Ordinativo Economico ASL)

VERIFICHE VISIVE, AMMINISTRATIVE E TECNICHE

A seguito delle operazioni di collaudo tecnico-amministrative effettuate, si dichiara che la fornitura e pertanto le relative apparecchiature/strumenti/dispositivi ed eventuali accessori e/o componenti risulta/risultano:

-CONFORMITÀ BOLLA DI CONSEGNA CON ORDINATIVO ECONOMICO	SI ☒	NO ☐
-CORRISPONDENZA DEL CONTENUTO CON IL DDT	SI ☒	NO ☐
-ASSENZA DANNI ESTERNI DELL'APPARECCHIATURA E/O ACCESSORI-COMPONENTI	SI ☒	NO ☐
-CORRISPONDENZA ALL'OFFERTA TECNICA ED ECONOMICA	SI ☒	NO ☐
-FUNZIONANTE/I ED IDONEA/E ALL'USO PREVISTO	SI ☒	NO ☐
-VERIFICA DI SICUREZZA ELETTRICA SUPERATA (CEI EN 62353)	SI ☒	NO ☐
-PRESENZA MANUALI D'USO IN LINGUA ITALIANA (depositato presso U.O. di ubicazione)	SI ☒	NO ☐
-PRESENZA CERTIFICATI CE E/O DICHIARAZIONI DI CONFORMITA'	SI ☒	NO ☐
-PERSONALE SANITARIO/TECNICO ADDESTRATO E FORMATO ALL'UTILIZZO	SI ☒	NO ☐

Note: _____

ESITO COLLAUDO

L'ESITO DEL COLLAUDO È DA RITENERSI

☒ **POSITIVO** ☐ **POSITIVO CON RISERVA** ☐ **NEGATIVO**

Note: _____

Per accettazione e conferma

Il Responsabile della U.O. assegnataria o delegato	BARBARA DITASIO *Nome e Cognome*	*Timbro e Firma*	24/10/25 *Data di convalida*
Il Referente Ditta Fornitrice e/o Specialist	PASCALI FEDERICO *Nome e Cognome*	*Firma*	24/10/25 *Data di convalida*
Il Referente S.I.C.E. (Servizio Ingegneria Clinica Esterno)	MATTEO CIPMANI *Nome e Cognome*	*Firma*	24/10/25 *Data di convalida*
Il Resp. Impianto Radiologico e/o _____	*Nome e Cognome*	*Firma*	___/___/___ *Data di convalida*
L'Esperto Specialista *(EQ-ER-ASL-altro)* _____	*Nome e Cognome*	*Firma*	___/___/___ *Data di convalida*
Altra figura: _____	*Nome e Cognome*	*Firma*	___/___/___ *Data di convalida*
Il DEC o Assistente al DEC *(Direttore Esecuzione Contratto)* _____	*Nome e Cognome*	*Firma*	___/___/___ *Data di convalida*

A.T.I. SIEMENS - H.C. HOSPITAL CIVILE SAN MARIANNA FBF Via [illegible] 65124 PESCARA Tel. 085 4253280 - Fax 085 4253284

Validazione definitiva esito procedura di collaudo con conferma data di inizio accettazione del bene

Il Collaudatore U.O.C. INGEGNERIA CLINICA-HTA	ASL PESCARA Antonio VERNA *Nome e Cognome*	ASL PESCARA UOC INGEGNERIA CLINICA-HTA IL COLLAUDATORE Antonio VERNA *Timbro e Firma*	24/10/25 *Data di convalida*

Allegati: ☒ Scheda Collaudo SICE ☐ Rapporto Tec. Ditta Fornitrice ☒ DdT ☒ Ordinativo Economico ☒ Documentazione Tecnica ☒ Certificati CE/Dich. Conformità ☐ Verifiche Sicurezza Elettrica ☐ _____ ☐ _____

Note: _____

OLYMPUS

OLYMPUS EUROPA SE & Co. KG c/o Arvato SE, Werner-Schröder-Straße 1, 21035 Hamburg
A nome di Olympus Italia S.r.l., Società Unipersonale, Via S. Bovio 1-3 - 20054 Segrate (MI)

Destinatario

AZIENDA U.S.L. DI PESCARA
ING.CLINICA C.O.ING. LOMELE
CELL.3351935581
VIA R. PAOLINI, 45
I-65124 PESCARA (PE)

Tel.: 0854251

35015899

Documento Di Trasporto

Data	**17.10.2025**
Codice Cliente	2000034419
Docum. Di Trasporto No.	**77174679**
VS. Riferimenti	20-2025-140
VS. Data Ordine	14.10.2025
NS. Conferma	0013658499
Reference	
ID:	UFEAZS

Causale Trasporto

POS	Codice Articolo	Descrizione	Your item code	T1/T2	Qtà Spedita
010	N6019450	GIF-1100 W/BS (EN) 2510118	04953170420207	T2	1

No. Colli **1**
Peso Lordo (kg) **4,75**

Per Ricevuta
21-10-25

Per ricevuta

X

Pe 24.10.'25

CONSEGNA PER CONTO DI OLYMPUS ITALIA S.r.l. - Società Unipersonale
Via S. Bovio 1-3 - 20054 Segrate (Milano)
Tel. 0039 02 26972-1 - Fax. 0039 02 26972-488
n° registro produttori AEE IT08020000002572
N° registro produttori pile IT09060P00000538

ATTENZIONE: controllare attentamente il numero e lo stato dei colli. Eventuali differenze e/o danni vanno contestati immediatamente al corriere annotando sulla bolla di consegna, in sua presenza, le irregolarità rilevate. I reclami relativi alla spedizione devono essere inoltrati in forma scritta ad Olympus tassativamente entro e non oltre 8 (otto) giorni dalla data di arrivo della merce, allegando copia del DDT ed eventuali altri documenti o foto a supporto. Decorso il termine sopra indicato la consegna si intenderà integralmente e perfettamente completata. Contattare Olympus per ulteriori informazioni.

A. S. L. PESCARA
VIA R. PAOLINI N.45
PESCARA (PE), ITALIA, CAP: 65124
C.F. e P.IVA 01397530682

Tel : (+39) 085
Fax :4521

ORDINE

RIF-ORDINE

NUMERO : 20-2025-140
DEL : 14/10/2025
DATA CONSEGNA :
DATA FINE CONSEGNA :

FORNITORE

Spett.le
(96295) OLYMPUS ITALIA SRL
P.I.: 10994940152

VIA MODIGLIANI, 45
20090 SEGRATE, MI
Telefono : 02/26972.1
FAX : 0226972353

Budget di Spesa : UAUT-2025-18/3 **Conto :** 0101020502 - Attrezzature generiche

Codice	Descrizione	UM	Quantita	Prezzo Unit.	%Sc	Imponibile	%IVA
364656	VIDEOGASTROSCOPIO HDTV EVIS X1	**NUM**	**1,00**	**27 838,04**	**0,00** **0,00**	**27 838,04**	**22,00**

OFFERTA ECONOMICA NR. 54941-3G-FY26-fe DEL 19/09/2025 - RDO ME.PA 5637679

CIG: B894F1CE97 - AGGIUDICAZIONE PROCEDURA RDO 5637679 ED AFFIDAMENTO FORNITURA VIDEOGASTROSCOPIO PEDIATRICO COMPATIBILE CON COLONNA ENDOSCOPICA OLYMPUS MOD.CV1500

Cdc: C05C03 UOC CHIRURGIA PEDIATRICA - PO PESCARA Q.tà 1,00

COD IVA	IVA%	IMPONIBILE	IMPOSTA
I22	22,00	27 838,04	6 124,37

TOTALE IMPONIBILE	TOTALE IVA	TOTALE ORDINE
27 838,04	6 124,37	33 962,41

Luogo consegna

LTCPE - MAGAZZINO TECNOLOGICO PESCARA
VIA R. PAOLINI, 47
PESCARA,65100

AZIENDA SANITARIA LOCALE DI PESCARA
Sede Legale: Via Renato Paolini, 45 - 65124 Pescara - P. IVA 01397530682 - www.asl.pe.it

AZIENDA SANITARIA LOCALE PESCARA

UOC INGEGNERIA CLINICA

DETERMINAZIONE DIRIGENZIALE

N. 3593 DEL 22/10/2025

OGGETTO: AGGIUDICAZIONE PROCEDURA ME.PA RDO NR.5637679 ED AFFIDAMENTO PER LA FORNITURA DI VIDEOGASTROSCOPIO PEDIATRICO COMPATIBILE CON COLONNA ENDOSCOPICA OLYMPUS MOD. CV1500 PER LE ESIGENZE DELLA UOC CHIRURGIA PEDIATRICA DEL P.O. DI PESCARA, A FAVORE DELLA DITTA OLYMPUS ITALIA SRL, AI SENSI DELL'ART.50, COMMA 1- LETTERA B) DEL D.LGS. 36/2023 - CIG: B894F1CE97.

DETERMINAZIONE DIRIGENZIALE

OGGETTO: AGGIUDICAZIONE PROCEDURA ME.PA RDO NR.5637679 ED AFFIDAMENTO PER LA FORNITURA DI VIDEOGASTROSCOPIO PEDIATRICO COMPATIBILE CON COLONNA ENDOSCOPICA OLYMPUS MOD. CV1500 PER LE ESIGENZE DELLA UOC CHIRURGIA PEDIATRICA DEL P.O. DI PESCARA, A FAVORE DELLA DITTA OLYMPUS ITALIA SRL, ai sensi dell'art.50, comma 1- lettera b) del D.Lgs. 36/2023 - CIG: B894F1CE97.

Nella sede dell'Azienda A.S.L. di Pescara, il Dott. Ing. Vincenzo Lo Mele Direttore UOC Ingegneria Clinica- HTA dell'ASL di Pescara, nominato con deliberazione del Direttore Generale n.1660 del 14 novembre 2023, nell'esercizio delle funzioni ad essa delegate, ha adottato la seguente determinazione dirigenziale:

PREMESSO che il servizio di manutenzione delle apparecchiature elettromedicali è di competenza dell'U.O.C. Ingegneria Clinica – HTA (DDG n°602/2019);

DATO ATTO che la fornitura in argomento non è inclusa nel servizio in uso nelle Strutture Sanitarie e nei Presidi Ospedalieri dell'Azienda ASL di Pescara, affidato alla RTI Siemens Healthcare/Facility Med/H.C. Hospital Consulting - Contratto Rep. n. 566 del 20/06/2019 e pertanto di competenza diretta della UOC Ingegneria Clinica della ASL di Pescara;

VISTA la richiesta a mezzo mail del 21/08/2025 da parte della dott.ssa M.T.I.– Coordinatore Gruppo di studio Microbiomica Clinica SIGENP Gastroenterologia ed Endoscopia Digestiva Pediatrica della UOC di Pediatria del P.O. di Pescara, con la quale esprimeva la necessità urgente di acquistare un videogastroscopio pediatrico compatibile con la colonna endoscopica Olympus mod. CV1500 che abbia un diametro di 8,5 mm circa per poter effettuare esami endoscopici nei bambini con meno di 3 anni e meno di 15kg di peso;

RITENUTA l'opportunità da parte della scrivente UOC Ingegneria Clinica della ASL di Pescara, di predisporre attraverso la piattaforma Me.Pa in data 18/09/2025, una Rdo nr.5637679 identificata quale "Trattativa Diretta", evidenziando l'operatore economico Olympus Italia srl, per la fornitura sopracitata, avente una base d'asta di € 28.000,00 oltre iva;

PERVENUTA in data 19/09/2025 l'offerta economica da parte della ditta Olympus Italia srl, per l'importo di € 27.838,04 oltre iva;

GENERATO il documento di stipula in data 13/10/2025 con la ditta Olympus Italia srl., per un importo di €27.838,04 oltre iva e dunque procedendo all'affidamento della fornitura in argomento, approvato dal Direttore U.O.C., Ingegneria Clinica – HTA Ing. Vincenzo Lo Mele, ai sensi dell'art.50, comma 1- lettera b) del D.Lgs. 36/2023;

ACQUISITO il codice CIG: B894F1CE97;

PRESO ATTO che la ditta affidataria provvederà ad emettere quanto previsto dalla L.136/2010 circa l'obbligo di tracciabilità dei flussi finanziari, contemporaneamente all'accettazione dell'affidamento.

IL DIRETTORE UOC INGEGNERIA CLINICA H.T.A

VISTO il D.lgs. 502/92 e s.m.i.;

VISTO il D.lgs. n. 165/01 e s.m.i.;

VISTA la delibera n. 705 del 28.06.2012 avente per oggetto "Approvazione del Regolamento Aziendale per la disciplina dei procedimenti di adozione delle Deliberazioni del Direttore Generale e delle Determinazioni dei Dirigenti immediatamente esecutive;

VISTO l'Atto Aziendale redatto ai sensi e per gli effetti dell'art. 3 comma 1 bis del D. Lgs. 19 giugno 1999 n. 229 modificativo del D.Lgs. 30 dicembre 1992 n. 502 e s.m.i. approvato con delibera del Direttore Generale di questa Azienda n. 220 del 02/03/2018;

VISTO L'art.50, comma 1- lettera b) del D.Lgs. 36/2023 e ss.mm.ii.;

DETERMINA

1. **DI CONSIDERARE** le premesse quali parti integranti e sostanziali del presente provvedimento;

2. **DI PRENDERE ATTO** della necessita di procedere con la fornitura di un videogastroscopio pediatrico compatibile con la colonna endoscopica Olympus mod. CV1500 che abbia un diametro di 8,5 mm circa per poter effettuare esami endoscopici nei bambini con meno di 3 anni e meno di 15kg di peso, presso la UOC di Chirurgia Pediatrica del P.O. di Pescara;

3. **DI APPROVARE** l'offerta economica del 19/09/2025 presentata dalla ditta Olympus Italia srl per un importo pari ad €27.838,04 oltre iva, approvato dal Direttore dell'Ingegneria Clinica HTA Ing. Vincenzo Lo Mele;

4. **DI AFFIDARE** l'intervento alla ditta Olympus Italia srl - ai sensi dell'art.50, comma 1- lettera b) del D.Lgs. 36/2023, al prezzo di € 27.838,04 oltre iva;

5. **DI DARE ATTO** che la somma complessiva di € 33.962,41 IVA compresa relativa al Servizio in argomento va registrata in contabilità Economico Patrimoniale del Bilancio 2025 come segue alla voce di conto 01.01.02.05.02 – Aut. 18/3;

6. **DI PUBBLICARE** il presente atto sul sito www.asl.pe.it link "Amministrazione trasparente" - settore 11 - bandi di gara e contratti- ai sensi e per gli effetti art. 37 co2, D.Lgs. n. 33/2013;

7. **DI DARE ATTO** che la documentazione completa relativa all'affidamento in argomento, i cui estremi sono citati in premessa, è custodita agli atti degli Uffici dell'Ingegneria Clinica – HTA dell'Azienda ASL di Pescara;

8. **DI CONFERIRE** al presente atto la clausola dell'immediata esecutività.

UOC INGEGNERIA CLINICA

L'Istruttore	Il Direttore
Francesca D'Orazio	Vincenzo Lo Mele firmato digitalmente

Voce di conto: 01.01.02.05.02 – Aut. 18/3 Anno : 2025

CERTIFICATO DI PUBBLICAZIONE

- Si attesta che il presente atto viene pubblicato, in forma integrale, all'ALBO ON LINE dell'ASL di Pescara (art. 32 L. 69/09 e s.m.i.), in data 23/10/2025 per un periodo non inferiore a 15 giorni consecutivi.

OLYMPUS
OLYMPUS
OLYMPUS

Descrizione: **VIDEOGASTROSCOPIO EVIS X1 HDTV OLYMPUS**
GIF-1100

Codice: **N6019450**

Modello: **GIF-1100**

Produttore:
OLYMPUS MEDICAL SYSTEM CORP.
2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Giappone

Anno immissione in commercio: 2020

Classificazione CND: Z12020510

RDM: 1997541

❑ *APPLICAZIONE*
Videogastroscopio progettato per esaminare endoscopicamente a scopo di diagnosi e terapia il tratto superiore (esofago, stomaco, duodeno) dell'apparato digerente.

❑ *DESCRIZIONE*
Il GIF-1100 è un videogastroscopio di nuova generazione ad alta definizione HDTV che, grazie alle sue caratteristiche ottiche, elettroniche e meccaniche, può svolgere attività routinarie ad alto livello di indagine ed operatività.
In associazione al videoprocessore CV-1500 e ad un monitor con risoluzione 4K UHD, l'immagine dello strumento viene rappresentata in risoluzione **4K**.
L'angolo di visione è di 140° e permette un rapido orientamento all'interno della cavità gastrica ed una rapida osservazione d'insieme. L'ampiezza del campo visivo consente all'operatore di sfruttare al meglio le angolazioni del tratto distale, riducendo i momenti di massimo sforzo e, di conseguenza, l'usura dei tiranti. Lo strumento fornisce una profondità di campo ottimale di **2-100 mm (CLOSE FOCUS)**. Questo garantisce una maggiore precisione nella visione ravvicinata dei particolari e un controllo della fuoriuscita dal canale bioptico degli accessori transendoscopici già a 3 mm dal distale con un impiego degli stessi in completa sicurezza. La presenza di un doppio fascio di fibre portaluce consente un'illuminazione sempre ottimale sia nei campi ravvicinati, sia nelle manovre di retrovisione; questa caratteristica elimina ogni effetto di ombre non desiderate durante l'impiego di accessori transendoscopici. Le angolazioni ed il diametro esterno consentono di effettuare agevolmente qualsiasi manovra diagnostica. Il gruppo comandi comprende i relativi meccanismi di blocco angolazioni per consentire il mantenimento della posizione del tratto angolabile durante la visione o le procedure di terapia. Il canale operativo (2.8 mm) permette l'agevole impiego di una vasta gamma di accessori transendoscopici. Il raggio di curvatura del tratto angolabile, durante la flessione massima di quest'ultimo, è stato ridotto al massimo per facilitare la manovrabilità in retroversione per la visione del cardias e in duodeno. Il canale di lavaggio ausiliario permette il lavaggio del campo operativo garantendo sicurezza e precisione nelle procedure operative. L'unità di controllo dello strumento dispone di **4 tasti funzione** per il controllo delle periferiche eventualmente abbinate o dei programmi di gestione dell'immagine forniti dal videoprocessore. Le funzioni possono essere liberamente scelte tra quelle disponibili e memorizzate per ogni differente operatore. La nuova sezione di controllo "**Ergo Grip**" è stata progettata per adattarsi

meglio agli utenti con mani più piccole. Il manipolo dal design ergonomico offre un'impugnatura comoda e stabile, un peso minore e maggiore facilità nel raggiungere le manopole di controllo dell'angolazione e gli interruttori dello strumento azionabili a 360°.
La sezione di controllo è stata inoltre disegnata riducendo al massimo cavità e rilievi in modo da rendere ancora più maneggevole lo strumento e da rendere agevole e sicura la pulizia e la disinfezione di questa parte dello strumento.
Lo strumento è dotato del nuovo ed innovativo connettore "**One Touch**" che permette una connessione digitale diretta dello strumento alla fonte di luce e al processore così da eliminare la necessità di collegare cavi al connettore. Sul connettore sono presenti tutti i contatti elettrici realizzati con una speciale lega anticorrosione. **Il connettore "One Touch" è completamente a tenuta (Waterproof)** non è più necessario l'utilizzo di un tappo di tenuta per il reprocessing dello strumento. Si riducono quindi i rischi di infiltrazione accidentale dello strumento. Inoltre il videogastroscopio **GIF-1100** è dotato di un microchip per l'identificazione dell'endoscopio e la sua tracciabilità: quando viene connesso al videoprocessore, esso rileva e scambia informazioni telemetriche, autoregolando la colorimetria in modo ottimale (bilanciamento automatico del bianco memorizzato sia per la visione endoscopica normale, sia per quella in modalità **NBI**), conteggiando il numero degli esami sostenuti dall'endoscopio e fornendo ulteriori informazioni utili all'assistenza tecnica (funzione di riconoscimento ID) .
La particolare microtelecamera (CCD) a codifica diretta del colore di cui è dotato questo strumento, permette di ottenere un'immagine endoscopica ad **alta definizione HDTV** ed elevata resa cromatica. Si possono avere due fattori di magnificazione elettronica (1.2x e 1.5x). Lo strumento è inoltre dotato della modalità **Narrow Band Imaging (NBI)**. **NBI** è un sistema di illuminazione che, sfruttando specifiche lunghezze d'onda della luce, permette di evidenziare il pattern vascolare delle mucose rendendo più facilmente visibili aree sospette e supportando la diagnosi precoce di lesioni e l'individuazione dei margini delle stesse. Ne deriva una migliore efficienza dell'esame o della procedura e un contributo alla diminuzione del numero di biopsie inutili.
Quando il GIF-1100 è utilizzato in combinazione con il videoprocessore **CV-1500 EVIS X1**, sono utilizzabili modalità di osservazione innovative:

- **BAI-MAC** (Brightness Adjustment Imaging with Maintenance of Contrast)
- **TXI** (TeXture and Color Enhancement Imaging)
- **RDI** (Red Dichromatic Imaging)

❑ *COMPATIBILITÀ*

Per un impiego corretto del videogastroscopio Olympus **GIF-1100** è necessario che questo sia abbinato a:

Strumenti	**Modelli compatibili esistenti**	
Videoprocessore	CV-190, CV-190 PLUS	CV-1500
Fonte di luce	CLV-190	
Monitor consigliati	OEV321UH	
Bottiglietta	MAJ-901, MAJ-902	

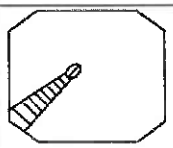
Si consigliano i seguenti complementi:

Strumenti	**Modelli compatibili esistenti**
Aspiratore consigliati	KV-6
Insufflatore di CO_2	UCR
Pompa di lavaggio	OFP-2, OFP-3, OFP-3 PLUS

❑ *UTILIZZO IN TERAPIA LASER e HF*

Lo strumento è totalmente compatibile con Laser Neodimio Yag e con procedure operative ad alta frequenza.

❑ *CARATTERISTICHE TECNICHE*

PROPRIETÀ OTTICHE	
Direzione di visione	Frontale 0°
Angolo di visione	140°
Profondità di campo	2-100 mm
Distanza minima visibile dell'accessorio dal distale	3 mm
Fasci di fibre incoerenti portaluce	2
Direzione di ingresso dell'accessorio nell'immagine endoscopica	

DIMENSIONI E PESO	
Diametro canale bioptico	2.8 mm
Diametro terminale distale	8.9 mm
Diametro tubo flessibile	8.9 mm
Angolazioni tratto angolabile	210°-90°Up-Down / 100°-100° Right-Left
Lunghezza operativa	1030 mm
Lunghezza totale	1350 mm
Peso	1.26 kg

CONDIZIONI AMBIENTALI DI FUNZIONAMENTO	
Temperatura	10°-40° C
Umidità relativa	30-85 %
Pressione atmosferica	700-1060 hPa

DOTAZIONE STANDARD			
ARTICOLO	**DESCRIZIONE**	**Q.TÀ**	**CODICE**
GIF-1100	Videogastroscopio HDTV Olympus	1	**N6019450**
MH-856	Raccordo pulizia manuale canale di aspirazione	1	**027800**
BW-412T	Spazzolino di pulizia combinato monouso	3	-
MH-944	Slitta di collegamento canali aria/acqua e aspirazione per pulizia manuale	1	**027803**
MH-438	Valvola aria/acqua	1	**N6174950**
MH-443	Valvola aspirazione	1	**027798**
MB-358	Valvola bioptica	1	-
MH-946	Sistema di irrigazione canale aria/acqua per pulizia manuale	1	**N3627300**
MH-948	Adattatore (pistoncino blu) per pulizia canale aria/acqua	1	**027801**
MAJ-855	Tubo di lavaggio per canale ausiliario	1	**N3499350**
MB-156	Tappo di ventilazione	1	**027706**
MB-142	Boccaglio pluriuso	2	**028725**
-	Valigia di trasporto con imbottitura preformata non disinfettabile per contenere lo strumento	1	-
-	Manuale d'uso	1	-
	Manuale di riprocessazione	1	-

- ***AVVERTENZE***

Prima dell'uso di questo strumento è opportuno leggere attentamente il manuale di istruzioni dello stesso e di tutte le attrezzature che verranno impiegate durante la procedura.

- ***PULIZIA, DISINFEZIONE, STERILIZZAZIONE***

Se lo strumento in oggetto non è consegnato in confezione sterile, sottoporlo a disinfezione e/o sterilizzazione secondo quanto indicato nel manuale di istruzioni.
È assolutamente necessario che lo strumento, dopo l'uso, venga sottoposto a decontaminazione e conservato secondo le indicazioni contenute nel manuale.
Una decontaminazione e/o una conservazione inadeguate possono determinare rischio di infezione, danneggiare l'attrezzatura o pregiudicare il rendimento della stessa.
Alta disinfezione ammessa con utilizzo di Acido Peracetico, Gluteraldeide o con utilizzo di autoclave ad Ossido di Etilene (seguire attentamente le istruzioni contenute nel manuale di reprocessing dello strumento)

❑ *NORME ELETTRICHE APPLICATE*

CEI EN 60601-1 (2007) (Apparecchi elettromedicali Parte 1: norme generali per la sicurezza)
CEI EN 60601-1-2 (2001) (Norma collaterale: EMC – Prescrizioni e prove)
CEI EN 60601-1-2 (2007) (Norma collaterale: EMC – Prescrizioni e prove)
CEI EN 60601-1-2 (2018) Gruppo 1, Classe B (Norma collaterale: EMC – Prescrizioni e prove)
CEI EN 60601-1-6 (2011) (Norma collaterale: Usabilità)
CEI EN 60601-1-9 / A1 (2016) (Norma collaterale: Prescrizioni per una progettazione ecologicamente consapevole)
CEI EN 60601-2-18 (1997) (Norme particolari per la sicurezza delle apparecchiature endoscopiche)
CEI EN 60601-2-18 (2016) (Prescrizioni particolari relative alla sicurezza fondamentale e alle prestazioni essenziali delle apparecchiature endoscopiche)
CEI EN 62366-1 (2016) (Dispositivi medici Parte 1: Applicazione dell'ingegneria delle caratteristiche utilizzative ai dispositivi medici)

PARTE APPLICATA TIPO BF

❑ *NORME APPLICATE*

UNI CEI EN ISO 14971 (2012) (Dispositivi medici - Applicazione della gestione dei rischi ai dispositivi medici)
UNI EN ISO 11135-1 (2008) (Sterilizzazione dei prodotti sanitari - Ossido di etilene - Requisiti per lo sviluppo, la convalida e il controllo sistematico di un processo di sterilizzazione per dispositivi medici)
UNI EN ISO 11135 (2014) (Sterilizzazione dei prodotti sanitari - Ossido di etilene - Requisiti per lo sviluppo, la convalida e il controllo sistematico di un processo di sterilizzazione per dispositivi medici)
UNI EN ISO 17664 (2005) (Sterilizzazione dei dispositivi medici - Informazioni che devono essere fornite dal fabbricante per i processi di dispositivi medici risterilizzabili)
UNI EN ISO 10993-1 (2010) (Valutazione biologica dei dispositivi medici - Parte 1: Valutazione e prove all'interno di un processo di gestione del rischio)
UNI EN ISO 10993-5 (2009) (Parte 5: Prove per la citotossicità in vitro)
UNI EN ISO 10993-7 (2022) (Parte 7: residui della sterilizzazione mediante ossido d'etilene)
UNI EN ISO 10993-10 (2010) (Parte 10: Prove di irritazione e sensibilizzazione cutanea)
UNI CEI EN ISO 15223-1 (2017) (Dispositivi medici - Simboli da utilizzare nelle etichette del dispositivo medico, nell'etichettatura e nelle informazioni che devono essere fornite - Parte 1: Requisiti generali)
UNI EN 1041 (2013) (Informazioni fornite dal fabbricante con i dispositivi medici)

❑ *DIRETTIVA CEE 93/42 PER I DISPOSITIVI MEDICI*

Classe IIa

❑ *ENTE CERTIFICATORE*

TÜV Rheinland Product Safety GmbH

CE 0197

❑ *GARANZIA*

Salvo diversamente indicato nella documentazione allegata, la strumentazione si intende garantita per 12 mesi dalla data di consegna e collaudo contro i difetti di fabbricazione.

❑ *IMBALLO*

Strumento fornito in valigia preformata non sanificabile

MATERIALE CONSUMABILE PER GIF-1100		
ARTICOLO	**DESCRIZIONE**	**CODICE**
MB-358	Confezione 10 valvole bioptiche pluriuso	**028794**
MAJ-1555	Confezione 20 valvole bioptiche sterili monouso	**N3043000**
MH-443	Valvola di aspirazione	**027798**
MH-438	Valvola aria/acqua	**N6174950**
MAJ-855	Tubo di lavaggio per canale ausiliario	**N3499350**

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.:	SX 2158445-1
Certificate Holder:	OLYMPUS MEDICAL SYSTEMS CORP. 2951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507 Japan
Scope:	Design and Development, Manufacture, Distribution, Service, Quality Assurance, Regulatory Affairs of Endoscopes, Endotherapy devices, Light Sources, Imaging Processors, Endoscope Position Detecting Units, Electrothermal Cautery Units, Integrated Endosurgery Systems, Endoscopic Regulation/Control Units, Camera Heads/Pumps/Monitors/Recorders for Endoscopy, Electrosurgical Equipment, Capsule Endoscopes and Systems, Laparoscopic Insufflators, Ultrasound Diagnostic Imaging Systems, Disinfecting Units, Ultrasound Surgical Equipment, Probes and Transducers for Ultrasonic Lithotriptors, Sterile Non Active Instruments used in conjunction with Endoscopes, Sterile Endotherapy Devices used in conjunction with Endoscopes, Sterile Non Active Devices used in conjunction with Medical Ultrasound Diagnostic Imaging Systems and Water Container, Water Supply Tube, Water Feeding valve and Foot Switch for Pump, Surgical Microscope

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.:	150293386-301
Effective date:	2024-07-27
Expiry date:	2027-07-26
Issue date:	2024-07-04

Replaces certificate SX 2158445-1 issued 2024-02-29

Atsushi Kato
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TÜVRheinland®
Precisely Right.

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.:	SX 2158445-1
Certificate Holder:	OLYMPUS MEDICAL SYSTEMS CORP. 2951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507 Japan

The scope of certification also covers the following sites:

No.	Facility	Scope
/01	c/o OLYMPUS MEDICAL SYSTEMS CORP. Ishikawa Facility 2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507 Japan	Design and Development, Service, Administration, Quality Assurance, Regulatory Affairs
/02	c/o OLYMPUS MEDICAL SYSTEMS CORP. Utsuki Facility 2-3, Kuboyama-cho, Hachioji-shi, Tokyo 192-8512 Japan	Design and Development of Endoscopes, Light Sources, Imaging Processors
/03	c/o OLYMPUS MEDICAL SYSTEMS CORP. Tatsuno Facility 6789 Inatomi, Tatsuno-machi, Kamiina-gun, Nagano 399-0428 Japan	Design and Development of Endoscopes
/04	c/o Olympus Medical Systems Corp. Hinode Facility 34-3 Hirai, Hinode-machi Nishitama-gun, Tokyo 190-0182 Japan	Design and Development and Quality Assurance of Endoscopes, Endotherapy devices, Imaging Processors, Endoscopic Regulation/Control Units, Camera Heads, Capsule Endoscopy Systems, Ultrasound Diagnostic Imaging Systems, Surgical Microscope, Water Container, Water Supply Tube, Water Feeding valve and Foot Switch for Endoscopes and Sterile Non Active Instrument used in conjunction with Endoscopes, and Sterile Non Active Devices used in conjunction with Medical Ultrasound Diagnostic Imaging Systems, IT Products used in conjunction with Medical Endoscopy Systems

Report No.:	150293386-301
Effective date:	2024-07-27
Expiry date:	2027-07-26
Issue date:	2024-07-04

Atsushi Kato
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TÜVRheinland®
Precisely Right.

Certificate

Quality Management System
EN ISO 13485:2016

Registration No.:	SX 2158445-1
Certificate Holder:	OLYMPUS MEDICAL SYSTEMS CORP. 2951 Ishikawa-cho Hachioji-shi, Tokyo 192-8507 Japan

The scope of certification also covers the following sites:

/05	c/o OLYMPUS MEDICAL SYSTEMS CORP. Shirakawa Facility 3-1 Okamiyama, Odakura, Nishigo-mura, Nishishirakawa-gun, Fukushima 961-8061 Japan	Design and Development and Quality Assurance of Light Sources, Imaging Processors, Endoscope Position Detecting Units, Electrothermal Cautery Units, Integrated Endosurgery Systems, Endoscopic Regulation/Control Units, Camera Heads/Pumps/Monitors/Recorders for Endoscopy, Electrosurgical Equipment, Laparoscopic Insufflators, Ultrasound Diagnostic Imaging Systems, Ultrasound Surgical Equipment and Endoscopes, Probes and Transducers for Ultrasonic Lithotriptors, Ultrasonic Lithotriptors, Capsule Endoscopes, Printed wiring boards for medical devices
/06	c/o OLYMPUS MEDICAL SYSTEMS CORP. Aizu Facility 3-1-1 Niiderakita, Aizuwakamatsu-shi, Fukushima 965-8520 Japan	Design and Development and Quality Assurance of Medical Endoscopes and Disinfecting Units, Probe for Endoscope Position Detecting Units
/07	c/o OLYMPUS MEDICAL SYSTEMS CORP. Aomori Facility 2-248-1 Okkonoki, Kuroishi-shi, Aomori 036-0357 Japan	Design and Development and Quality Assurance of Endotherapy devices, Ultrasound Surgical Equipment, Sterile Non Active Instruments used in conjunction with Endoscopes and Ultrasound Imaging Systems, and Sterile Endotherapy Devices used in conjunction with Endoscopes

Report No.:	150293386-301
Effective date:	2024-07-27
Expiry date:	2027-07-26
Issue date:	2024-07-04

Atsushi Kato
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

TÜVRheinland®
Precisely Right.

TÜVRheinland

EC Certificate

Directive 93/42/EEC Annex II, excluding Section 4
Full Quality Assurance System
Medical Devices

Registration No.: HD 60149405 0001

Report No.: 12018179 053

Manufacturer:
OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo
192-8507 Japan

Products:
Design and Development, Manufacture of Medical Endoscopy Systems, Diagnostic, Operation and Treatment Products

(see attachments for products included)

Replaces Approval, Registration No.: HD 60144066 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex II, excluding section 4 of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex II, section 5 of the aforementioned directive. For placing on the market of class III devices covered by this certificate an EC design-examination certificate according to Annex II, section 4 is required.

Effective Date: 2020-05-12

Date: 2020-05-12

Notified Body

m.aihara

M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

TÜVRheinland

Doc. I/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: HD 60149405 0001
Report No.: 12018179 053

Manufacturer: OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo
192-8507 Japan

Products included:

Medical Endoscopy Systems:
-Endoscopes
-Endotherapy Devices
-Imaging Processors
-Pumps for Endoscopy
-Light Sources
-Position Detecting Units
-Electrothermal Cautery Units
-Integrated Endosurgery Systems
-Endoscopic Regulation/Control Units
Electrosurgical Equipment
Probes and Transducers for Ultrasonic Lithotriptors
Laparoscopic Insufflators
Ultrasound Surgical Equipment
Ultrasonic Surgical System generator
Ultrasonic Surgical System transducer
Hard-tissue ultrasonic surgical system holder/tip
Disinfecting Units
Capsule Endoscopes and Systems
Ultrasound Diagnostic Imaging Systems

Notified Body

Date: 2020-05-12

M.Sc. M. Aihara

TÜVRheinland®

EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60144068 0001

Report No.: 12018179 052

Manufacturer:
OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho,
Hachioji-shi, Tokyo
192-8507 Japan

Products:
Sterile Endotherapy Devices used in conjunction with Endoscopes, Sterile Non Active Instruments used in conjunction with Endoscopes and Sterile Non Active Instruments used in conjunction with Medical Ultrasound Diagnostic Imaging Systems
Replaces Approval, Registration No.: DD 60123877 0001

Expiry Date: 2024-05-26

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2019-10-31

Date: 2019-10-31

Notified Body

TÜVRheinland

M.Aihara

M.Sc. M. Aihara

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.:	HZ 2158445-1
Manufacturer:	**OLYMPUS MEDICAL SYSTEMS CORP.** 2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507 Japan
EUDAMED Single Registration No :	JP-MF-000008016
Products:	Products of class IIa: Z120204 - INSTRUMENTS FOR THE ACQUISITION AND MANAGEMENT OF ENDOSCOPIC AND MINIMALLY INVASIVE SURGERY IMAGES A019007 - SCLEROTHERAPY NEEDLES AND KITS G030801 - GASTROINTESTINAL ENDOSCOPY, FORCEPS, SINGLE-USE G0380 - DIGESTIVE ENDOSCOPY DEVICES - ACCESSORIES Z120782 - GASTROENTEROLOGY INSTRUMENTS - SOFTWARE ACCESSORIES R070201 - BRONCHOSCOPIC SURGERY FORCEPS, SINGLE-USE U030301 - FORCEPS FOR UROGENITAL ENDOSCOPY, SINGLE-USE Z110401 - ULTRASOUND SCANNERS Z120290 - VARIOUS INSTRUMENTS FOR ENDOSCOPY AND MINI-INVASIVE SURGERY K010201 - MINIMALLY INVASIVE SURGERY SURGICAL INSTRUMENTS, SINGLE-USE G030501 - DIGESTIVE ENDOSCOPY, RETRIEVAL DEVICES Z120205 - UPPER GASTROINTESTINAL TRACT ENDOSCOPY INSTRUMENTS Z120206 - LOWER GASTROINTESTINAL TRACT ENDOSCOPY INSTRUMENTS Z120208 - ULMONARY ENDOSCOPIC INSTRUMENTS

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	150262093-307
Effective date:	2023-07-31
Expiry date:	2026-03-25
Issue date:	2023-07-31

TÜV Rheinland LGA Products GmbH Zertifizierstelle

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.: HZ 2158445-1

Manufacturer: **OLYMPUS MEDICAL SYSTEMS CORP.**
2951 Ishikawa-cho
Hachioji-shi, Tokyo
192-8507 Japan

Products of class IIb.
Z120204 - INSTRUMENTS FOR THE ACQUISITION AND MANAGEMENT OF ENDOSCOPIC AND MINIMALLY INVASIVE SURGERY IMAGES
Intended Purpose: Medical control unit for endo-surgery has been designed to be used with an Olympus endoscope and ancillary equipment for central operation, central display, automatic initial setting, and interlocking operation of the ancillary equipment.
Z120108 - GENERAL AND MULTIDISCIPLINARY SURGERY INSTRUMENTS INSTRUMENTS FOR ULTRASONIC SURGERY
Intended Purpose: The Electrosurgical & Ultrasonic Generator (USG-410) is intended to be used with the THUNDERBEAT Transducer, the SONICBEAT Transducer, the THUNDERBEAT or the SONICBEAT for open, laparoscopic (including single-site surgery), and endoscopic surgery to cut (dissect) or coagulate soft tissue or to ligate (seal and cut) vessels.
Z120109 - GENERAL AND MULTIDISCIPLINARY SURGERY INSTRUMENTS ELECTROSURGICAL INSTRUMENTS
Intended Purpose: The Electrosurgical & Ultrasonic Generator (USG-410) is intended to be used with the THUNDERBEAT Transducer, the SONICBEAT Transducer, the THUNDERBEAT or the SONICBEAT for open, laparoscopic (including single-site surgery), and endoscopic surgery to cut (dissect) or coagulate soft tissue or to ligate (seal and cut) vessels

Authorised representative(s): **Olympus Europa SE & Co.KG**
Wendenstrasse 20, 20097
Hamburg, Germany

Report No.: 150262093-307

Effective date: 2023-07-31

Expiry date: 2026-03-25

Issue date: 2023-07-31

TÜV Rheinland LGA Products GmbH

M. Aihara

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland

Registration No.: HZ 2158445-1

Manufacturer: **OLYMPUS MEDICAL SYSTEMS CORP.**
2951 Ishikawa-cho
Hachioji-shi, Tokyo
192-8507 Japan

Certificate history		
Revision:	Description:	Issue date:
0	Initial	2021-03-26
1	Added products: A019007, G030801, G0380 Changed address of Authorised representative	2021-08-29
2	Added product: Z120204 (class IIb)	2021-09-24
3	Added product: Z120782	2021-10-22
4	Added products: R070201, U090301	2022-01-10
5	Added product: Z110401	2022-04-27
6	Added product: Z120290 EMDN description amendment: Class IIa Z120204, A019007, G0380, Z120782, R070201, U090301, Class IIb Z120204	2022-09-29
7	Added product: K010201	2022-09-30
8	Added product: G030501	2022-09-30
9	Added products: Z120205, Z120206, Z120208	2023-06-09
10	Added products: Class IIb Z120108, Z120109	2023-07-31

Report No.: 150262093-307

Effective date: 2023-07-31

Expiry date: 2026-03-25

Issue date: 2023-07-31

M. Aihara

Michiaki Aihara
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

Certificate

TÜVRheinland®

Quality Management System
EN ISO 13485:2016

Registration No.: SX 2066607-1

Organization: Olympus Medical Systems Corp.
Hinode Plant
34-3 Hirai, Hinode-machi
Nishitama-gun, Tokyo
190-0182 Japan

Scope: Design and Development, Manufacture and Servicing of Endoscopes, Endotherapy devices, Imaging Processors, Endoscopic Regulation/Control Units, Camera Heads, Capsule Endoscopy Systems, Ultrasound Diagnostic Imaging Systems

Design and Development, Manufacture of Ultrasound surgical system transducer, Hard-tissue ultrasonic surgical system holder/tip, Surgical Microscope, Water Container, Water Supply Tube, Water Feeding Valve and Foot Switch for Endoscopes and Sterile Non Active Instrument used in conjunction with Endoscopes, and Sterile Non Active Devices used in conjunction with Medical Ultrasound Diagnostic Imaging systems

Design and Development of IT Products used in conjunction with Medical Endoscopy Systems

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.: 150242493-301
Effective date: 2021-10-12
Expiry date: 2024-10-11
Issue date: 2021-10-11

TÜV Rheinland LGA Products GmbH TÜVRheinland® Zertifizierungsstelle

Ning Chang

Ning N. C. Chang
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-14169-01-02

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho
Hachioji-shi
Tokyo
192-8507
Japan

31st May 2024

Notified Body Confirmation Letter

Reference: EU2023-607/838139

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, **BSI Group The Netherlands B.V.**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **2797** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-Cho
Hachioji-shi
Tokyo
192-8507
Japan

SRN Number: JP-MF-000008016

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of BSI Group The Netherlands B.V.,

Graeme Tunbridge

Graeme Tunbridge
Senior Vice President, Medical Devices

bsi.

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
DISPOSABLE BALLOON CATHETER **B5-2C**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
DISPOSABLE BALLOON CATHETER **B7-2C**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
DISPOSABLE CYTOLOGY BRUSH **BC-17W**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
DISPOSABLE CYTOLOGY BRUSH **BC-202D-1210** **BC-202D-2010** **BC-202D-3010** **BC-202D-5010** **BC-203D-2006**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
DISPOSABLE CYTOLOGY BRUSH **BC-201C-1006**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Single Use Cytology Brush **BC-205D-2010**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Cytology Brush V **BC-V600P-3010**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Guide Sheath Kit **K-402**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Guide Sheath Kit **K-403**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Guide Sheath Kit **K-404**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Aspiration Needle **NA-201SX-4021**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Aspiration Needle **NA-201SX-4022**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Aspiration Needle NA **NA-401D-1321** **NA-401D-1521** **NA-411D-1321** **NA-411D-1521**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Aspiration Needle NA2 **NA-601D-1519**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Single Use Aspiration Needle **NA-U200H-8019** **NA-U200H-8019S** **NA-U200H-8022** **NA-U200H-8022S**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Aspiration Needle **NA-U200H-8025**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Aspiration Needle **NA-U201H-8019** **NA-U201H-8022** **NA-U201H-8025**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Aspiration Needle **NA-U401SX-4021** **NA-U401SX-4022**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Aspiration Needle **NA-U401SX-4025N**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Guide Sheath Kit **K-401**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Aspiration Needle **NA-421C-1321** **Single Use Aspiration Needle** **NA-431C-1321** **NA-421C-1321** **NA-431C-1321**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
FLEXIBLE TROCAR 8mm **MAJ-1058**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Single Use Balloon Dilator V (with Knife) **BD-VC431Q-1840-20** **BD-VC431Q-1840-25** **BD-VC431Q-1840-30**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Balloon Dilator V (with Knife) **BD-VC431Q-1240-20** **BD-VC431Q-1240-25** **BD-VC431Q-1240-30**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
DISPOSABLE HOT BIOPSY FORCEPS **FD-210U** **FD-230U**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Hot Biopsy Forceps **FD-231C**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Electrosurgical Hemostatic Forceps **FD-410LR** **FD-411QR** **FD-411UR** **FD-412LR**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
DISPOSABLE EMR KIT **K-001** **K-002** **K-003** **K-004** **K-005** **K-006** **K-007**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
K-008 **K-009** **K-010** **K-011** **K-012**			
Single Use Electrosurgical Knife **KD-610L**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Electrosurgical Knife **KD-611L**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Electrosurgical Knife **KD-612L** **KD-612U**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Electrosurgical Knife **KD-620LR** **KD-620QR** **KD-620UR**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Electrosurgical Knife **KD-625LR** **KD-625QR** **KD-625UR**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Electrosurgical Knife **KD-640L**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Electrosurgical Knife **KD-645L**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Electrosurgical Knife **KD-650L**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
KD-650Q **KD-650U**			
Single Use Electrosurgical Knife **KD-655L** **KD-655Q** **KD-655U**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use 3-Lumen Sphincterotome V **KD-V410V-0720**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use 3-Lumen Sphincterotome V **KD-V411M-0320** **KD-V411M-0330** **KD-V411M-0720** **KD-V411M-0725** **KD-V411M-0730** **KD-V411M-1520** **KD-V411M-1530** **KD-V411M-3030** **KD-V431M-0720** **KD-V431M-0730**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use 3-Lumen Needle Knife V **KD-V440V**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use 3-Lumen Needle Knife V **KD-V441M** **KD-V451M**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Preloaded Sphincterotome V **KD-V611M-07201A** **KD-V611M-07201S** **KD-V611M-07202A** **KD-V611M-07202S** **KD-V611M-07251A** **KD-V611M-07251S**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
KD-V611M-07252A **KD-V611M-07252S** **KD-V611M-07301A** **KD-V611M-07301S** **KD-V611M-07302A** **KD-V611M-07302S** **KD-V631M-07201A** **KD-V631M-07201S** **KD-V631M-07202A** **KD-V631M-07202S** **KD-V631M-07301A** **KD-V631M-07301S** **KD-V631M-07302A** **KD-V631M-07302S**			
Single Use Sphincterotome V (Distal Wireguided) **KD-VC411Q-0320** **KD-VC411Q-0330** **KD-VC411Q-0720** **KD-VC411Q-0730** **KD-VC412Q-0215** **KD-VC431Q-0720** **KD-VC431Q-0730** **KD-VC433Q-0720** **KD-VC433Q-0730**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Preloaded Sphincterotome V (Distal Wireguided) **KD-VC611Q-07201A** **KD-VC611Q-07201S** **KD-VC611Q-07203A** **KD-VC611Q-07203S** **KD-VC611Q-07301A** **KD-VC611Q-07301S** **KD-VC611Q-07303A** **KD-VC611Q-07303S** **KD-VC631Q-07201A** **KD-VC631Q-07201S** **KD-VC631Q-07203A** **KD-VC631Q-07203S** **KD-VC631Q-07301A** **KD-VC631Q-07301S** **KD-VC631Q-07303A** **KD-VC631Q-07303S**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
SONICBEAT 5 mm, 20/35/45cm, Front-actuated Grip **SB-0520FC** **SB-0535FC** **SB-0545FC**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
THUNDERBEAT 5 mm, 10/20/35 cm, Inline Grip **TB-0510IC** **TB-0520IC** **TB-0535PC**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
DISPOSABLE ELECTROSURGICAL SNARE **SD-210U-10** **SD-210U-15** **SD-210U-25** **SD-221L-25** **SD-221U-25**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
DISPOSABLE ELECTROSURGICAL SNARE **SD-230U-20**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Electrosurgical Snare **SD-400U-10** **SD-400U-15**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
THUNDERBEAT Open Fine Jaw **TB-0009OF**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
THUNDERBEAT 5 mm, 20/35/45 cm, Front-actuated Grip Type S **TB-0520FCS** **TB-0535FCS** **TB-0545FCS**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
THUNDERBEAT Open Extended Jaw **TB-0920OE**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
SONICBEAT Transducer **TD-SB400**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
THUNDERBEAT Transducer **TD-TB400**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
DISPOSABLE ELECTROSURGICAL SNARE **SD-240U-10** **SD-240U-15** **SD-240U-25**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
THUNDERBEAT Open Fine Jaw Type X **TB-0009OFX**	Class IIb excluding Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
Balloon **MAJ-1351**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
Single Use Adapter Biopsy Valve **MAJ-1414**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
BALLOON 3 **MAJ-233**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
BALLOON 3 **MAJ-249**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
DISPOSABLE BENDING CANNULA **PR-233Q**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
Single Use Cannula V **PR-V214Q** **PR-V216Q** **PR-V220Q** **PR-V223Q** **PR-V414Q** **PR-V416Q** **PR-V418Q** **PR-V420Q** **PR-V427Q** **PR-V434Q** **PR-V435Q**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
Single Use Cannula V **PR-V434Y**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
Single Use 2-Lumen Cannula V **PR-V614M**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
Single Use Spray Catheter **PW-205V**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
Single Use 3-Lumen Extraction Balloon V **B-V232P-A** **B-V232P-B** **B-V242Q-A** **B-V242Q-B** **B-V432P-A** **B-V432P-B** **B-V442Q-A** **B-V442Q-B**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Single Use 3-Lumen Extraction Balloon V **B-V233V-A**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
Single Use Biliary Balloon Dilator **BD-210N-0420** **BD-210N-0440** **BD-210N-0620** **BD-210N-0640** **BD-210N-0830**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
Single Use Mechanical Lithotriptor V **BML-V232QR-26** **BML-V232QR-30** **BML-V242QR-30** **BML-V437QR-30** **BML-V442QR-30**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
DISPOSABLE DISTAL ATTACHMENT **D-201-10704** **D-201-11304** **D-201-11802** **D-201-11804** **D-201-12402** **D-201-12704** **D-201-13404** **D-201-14304** **D-201-15004** **D-201-16403**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
DISPOSABLE DISTAL ATTACHMENT **D-206-02** **D-206-03** **D-206-04** **D-206-05** **D-206-06**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
Single Use Grasping Forceps FG **FG-460YR**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
SINGLE USE GRASPING FORCEPS **FG-600U**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
Single Use Retrieval Basket V **FG-V421PR** **FG-V422PR** **FG-V431P** **FG-V432P**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
Single Use Retrieval Basket V **FG-V421YR**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
Single Use Retrieval Nitinol Basket V **FG-V451P**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
Single Use Loop Cutter **FS-410U**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
Single Use Reloadable Clip Applicator **HX-810LR** **HX-810QR** **HX-810UR**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
Single Use Grasping Forceps FG-253SX **FG-253SX**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
Single Use Rotatable Grasping Forceps FG-244NR **FG-244NR**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
Single Use Grasping Forceps FG-232L **FG-232L**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Single Use Grasping Forceps FG-220P **FG-220P**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
Single Use Grasping Forceps FG-214P **FG-214P**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
Single Use Grasping Forceps FG-804L **FG-804L**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
Single Use Mechanical Lithotriptor BML-610A **BML-610A**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
Single Use Injector NM-221C-0427 **NM-221C-0427**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Rotatable Clip Fixing Device **HX-201YR-135**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Repositionable Clip **HX-202LR** **HX-202UR**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Clip **HX-610-090**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Long Clip **HX-610-090L**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Short Clip **HX-610-090S**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Colored Short Clip **HX-610-090SC**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Clip **HX-610-135**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Long Clip **HX-610-135L**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Short Clip **HX-610-135S**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Super Short Clip **HX-610-135XS**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Biliary Stent V **PBD-V621R-1005** **PBD-V621R-1007** **PBD-V621R-1009** **PBD-V621R-1012** **PBD-V621R-1015**	Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197
Biliary Drainage Tube **PBD-421-1004** **PBD-421-1005** **PBD-421-1006** **PBD-421-1007** **PBD-421-1008** **PBD-421-1009** **PBD-421-1010** **PBD-421-1011** **PBD-421-1012** **PBD-421-1013** **PBD-421-1014** **PBD-421-1015**	Class IIb implantable non-WET	N/A	Certificate # HD 60149405 0001; NB# 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Single Use Stent Insertion Kit V **MAJ-1818** **MAJ-1819** **MAJ-1820** **MAJ-1821**	Class I device placed on the market in sterile condition	N/A	Certificate # DD 60144068 0001; NB# 0197
Single Use Injector **NM-400L-0421** **NM-400L-0621** **NM-400L-0423** **NM-400L-0523** **NM-400L-0623** **NM-400L-0425** **NM-400L-0525** **NM-400L-0625** **NM-400U-0323** **NM-400U-0423** **NM-400U-0523** **NM-400U-0623** **NM-400U-0425** **NM-400U-0525** **NM-400U-0625** **NM-400Y-0423** **NM-401L-0423** **NM-401L-0523** **NM-401L-0623** **NM-401L-0425** **NM-401L-0525** **NM-401L-0625**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Biopsy Forceps **FB-225U** **FB-235U** **FB-245U**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
DISPOSABLE BIOPSY FORCEPS **FB-210K/U** **FB-220K/U** **FB-230K/U** **FB-240K/U**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
DISPOSABLE BIOPSY FORCEPS **FB-211K** **FB-221K** **FB-231K** **FB-241K**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
DISPOSABLE BIOPSY FORCEPS **FB-212U** **FB-222U** **FB-232U** **FB-242U** **FB-214U** **FB-224U** **FB-234U** **FB-244U**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Biopsy Forceps FB-237Z **FB-237Z**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
SINGLE USE LIGATING DEVICE **HX-400U-30**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
DISPOSABLE BIOPSY FORCEPS **FB-211D** **FB-221D** **FB-231D** **FB-241D**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Biopsy Forceps FB-433D **FB-433D**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
DISPOSABLE GRASPING FORCEPS **FG-51D** **FG-52D** **FG-54D**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
FG-55D			
Single Use Guiding Device **CC-220DR**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Grasping Forceps LA **LA-201** **LA-202**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Surgical Scissors FS-200 **FS-200L**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Biopsy Forceps FB-420K **FB-420K**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
SINGLE USE AIR/WATER, SUCTION, & BIOPSY VALVE KIT (Sterile) **MAJ-2287**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Injector NM600/610 **NM-600L-0421** **NM-600L-0521** **NM-600L-0621** **NM-600L-0423** **NM-600L-0523** **NM-600L-0623** **NM-600L-0425** **NM-600L-0525** **NM-600L-0625** **NM-610L-0421** **NM-610L-0521** **NM-610L-0621** **NM-610L-0423** **NM-610L-0523** **NM-610L-0623** **NM-610L-0425** **NM-610L-0525**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
NM-610L-0625 **NM-610L-0426** **NM-610U-0323** **NM-610U-0423** **NM-610U-0523** **NM-610U-0623** **NM-610U-1825** **NM-610U-0325** **NM-610U-0425** **NM-610U-0525** **NM-610U-0625** **NM-610U-1826** **NM-610U-0326** **NM-610U-0426**			
Single Use Biopsy Forceps **FB-215U**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197
Single Use Biopsy Forceps FB-456D **FB-456D**	Class IIa	N/A	Certificate # HD 60149405 0001; NB# 0197

Confirmation Letter Revision History

Date	Action
2024/04/26	Initial issue
2024/05/31	Addition of Model BML-V437QR-30 to device group Single Use Mechanical Lithotriptor V

Business Stream Products
Certification Department

TÜVRheinland
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

OLYMPUS MEDICAL SYSTEMS CORP.
2951 Ishikawa-cho, Hachioji-shi
Tokyo 192-8507
Japan

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date April 30, 2024

Notified Body Confirmation Letter
Reference. : OMSC_MDR Application 2024-04-16; order # 150294495

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices.

This letter confirms that **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

OLYMPUS MEDICAL SYSTEMS CORP
2951 Ishikawa-cho, Hachioji-shi
Tokyo, 192-8507
Japan
SRN Number: JP-MF-000008016

The devices covered by the formal application and the written agreement mentioned above are identified in the tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by March 20, 2023 for the relevant devices.

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body

Ning Chang

Ning N. C. Chang
Certification body

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
VIDEO SYSTEM CENTER OLYMPUS CV-170	Class IIa	VIDEO SYSTEM CENTER OLYMPUS CV-170	Certificate # HD 60149405 0001 NB # 0197
Single Use Injector NM-600L-0421, NM-600L-0521, NM-600L-0621, NM-600L-0423, NM-600L-0523, NM-600L-0623, NM-600L-0425, NM-600L-0525, NM-600L-0625, NM-610L-0421, NM-610L-0521, NM-610L-0621, NM-610L-0423, NM-610L-0523, NM-610L-0623, NM-610L-0425, NM-610L-0525, NM-610L-0625, NM-610L-0426, NM-610U-0323, NM-610U-0423, NM-610U-0523, NM-610U-0623, NM-610U-1825, NM-610U-0325, NM-610U-0425, NM-610U-0525, NM-610U-0625, NM-610U-1826, NM-610U-0326, NM-610U-0426	Class IIa	Single Use Injector NM-600L-0421	Same as above

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Single Use Biopsy Forceps FB-215U, FB-216U	Class IIa	Single Use Biopsy Forceps FB-215U	Same as above
MEDICAL CONTROL UNIT FOR ENDOSURGERY UCES-4	Class IIb	MEDICAL CONTROL UNIT FOR ENDOSURGERY UCES-4	Same as above
WATER CONTAINER MAJ-901	Class IIa	WATER CONTAINER MAJ-901	Same as above
ENDOCAPSULE SOFTWARE 10 MAJ-2188	Class IIa	ENDOCAPSULE SOFTWARE 10 MAJ-2188	Same as above
ENDOCAPSULE SOFTWARE 10 LIGHT MAJ-2189	Class IIa	ENDOCAPSULE SOFTWARE 10 LIGHT MAJ-2189	Same as above
ENDOCAPSULE SOFTWARE 10 UPGRADE PACKAGE MAJ-2190	Class IIa	ENDOCAPSULE SOFTWARE 10 UPGRADE PACKAGE MAJ-2190	Same as above
Single Use Biopsy Forceps FB-456D (EMDN: R070201)	Class IIa	Single Use Biopsy Forceps FB-456D	Same as above
Single Use Biopsy Forceps FB-456D (EMDN: U090301)	Class IIa	Single Use Biopsy Forceps FB-456D	Same as above
ULTRASONIC BIPOLAR GENERATOR USG-410 (EMDN: Z120108)	Class IIb	ULTRASONIC BIPOLAR GENERATOR USG-410	Same as above
ULTRASONIC BIPOLAR GENERATOR USG-410 (EMDN: Z120109)	Class IIb	ULTRASONIC BIPOLAR GENERATOR USG-410	Same as above
URETERO-RENO FIBERSCOPE URF-P7	Class IIa	URETERO-RENO FIBERSCOPE URF-P7	Same as above
URETERO-RENO FIBERSCOPE URF-P7R	Class IIa	URETERO-RENO FIBERSCOPE URF-P7R	Same as above
Luer-Split MAJ-2092	Class IIa	Luer-Split MAJ-2092	Same as above
GASTROINTESTINAL VIDEOSCOPE GIF-1100	Class IIa	GASTROINTESTINAL VIDEOSCOPE GIF-1100	Same as above
COLONOVIDEOSCOPE CF-HQ1100DL/I	Class IIa	COLONOVIDEOSCOPE CF-HQ1100DL	Same as above
BRONCHOVIDEO SCOPE BF-1TH1100	Class IIa	BRONCHOVIDEO SCOPE BF-1TH1100	Same as above
SINGLE USE SPLINTING TUBE ST-SB1S	Class IIa	SINGLE USE SPLINTING TUBE ST-SB1S	Same as above
CYSTO-NEPHRO VIDEOSCOPE CYF-VH	Class IIa	CYSTO-NEPHRO VIDEOSCOPE CYF-VH	Same as above
RHINO-LARYNGO VIDEOSCOPE	Class IIa	RHINO-LARYNGO VIDEOSCOPE	Same as above

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB identification
ENF-VT3		ENF-VT3	
BRONCHOVIDEOSCOPE OLYMPUS BF-1TH1200	Class IIa	BRONCHOVIDEOSCOPE OLYMPUS BF-1TH1200	Same as above
EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-1TH190	Class IIa	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-1TH190	Same as above
BRONCHOVIDEOSCOPE OLYMPUS BF-1TQ170	Class IIa	BRONCHOVIDEOSCOPE OLYMPUS BF-1TQ170	Same as above
BRONCHOVIDEOSCOPE OLYMPUS BF-H1100	Class IIa	BRONCHOVIDEOSCOPE OLYMPUS BF-H1100	Same as above
BRONCHOVIDEOSCOPE OLYMPUS BF-H1200	Class IIa	BRONCHOVIDEOSCOPE OLYMPUS BF-H1200	Same as above
EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-H190	Class IIa	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-H190	Same as above
EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F	Class IIa	EVIS EXERA III BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP190F	Same as above
EVIS LUCERA ELITE BRONCHOFIBERVIDEO SCOPEOLYMPUS BF-MP290F	Class IIa	EVIS LUCERA ELITE BRONCHOFIBERVIDEOSCOPE OLYMPUS BF-MP290F	Same as above
EVIS EXERA III BRONCOVIDEOSCOPE OLYMPUS BF-P190	Class IIa	EVIS EXERA III BRONCOVIDEOSCOPE OLYMPUS BF-P190	Same as above
EVIS LUCERA ELITE BRONCHOVIDEOSCOPE OLYMPUS BF-P290	Class IIa	EVIS LUCERA ELITE BRONCHOVIDEOSCOPE OLYMPUS BF-P290	Same as above
BRONCHOVIDEOSCOPE OLYMPUS BF-Q170	Class IIa	BRONCHOVIDEOSCOPE OLYMPUS BF-Q170	Same as above
EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-Q190	Class IIa	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-Q190	Same as above
EVIS EUS ULTRASOUND BRONCHOFIBERVIDEO SCOPE OLYMPUS BF-UC190F	Class IIa	EVIS EUS ULTRASOUND BRONCHOFIBERVIDEO SCOPE OLYMPUS BF-UC190F	Same as above
EVIS EUS ULTRASOUND BRONCHOFIBERVIDEO SCOPE OLYMPUS BF-UC290F	Class IIa	EVIS EUS ULTRASOUND BRONCHOFIBERVIDEO SCOPE OLYMPUS BF-UC290F	Same as above
EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XP190	Class IIa	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XP190	Same as above
EVIS LUCERA ELITE BRONCHOVIDEOSCOPE OLYMPUS BF-XP290	Class IIa	EVIS LUCERA ELITE BRONCHOVIDEOSCOPE OLYMPUS BF-XP290	Same as above
EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XT190	Class IIa	EVIS EXERA III BRONCHOVIDEOSCOPE OLYMPUS BF-XT190	Same as above
COLONOVIDEOSCOPE	Class IIa	COLONOVIDEOSCOPE	Same as above

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
OLYMPUS CF-EZ1500DI		OLYMPUS CF-EZ1500DI	
COLONOVIDEOSCOPE OLYMPUS CF-EZ1500DL	Class IIa	COLONOVIDEOSCOPE OLYMPUS CF-EZ1500DL	Same as above
COLONOVIDEOSCOPE OLYMPUS CF-H170I	Class IIa	COLONOVIDEOSCOPE OLYMPUS CF-H170I	Same as above
COLONOVIDEOSCOPE OLYMPUS CF-H170L	Class IIa	COLONOVIDEOSCOPE OLYMPUS CF-H170L	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS CF-H185I	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS CF-H185I	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS CF-H185L	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS CF-H185L	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS CF-H190I	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS CF-H190I	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS CF-H190L	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS CF-H190L	Same as above
EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS CF-H290ECI	Class IIa	EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS CF-H290ECI	Same as above
EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS CF-H290I	Class IIa	EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS CF-H290I	Same as above
EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS CF-H290L	Class IIa	EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS CF-H290L	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS CF-HQ190I	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS CF-HQ190I	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS CF-HQ190L	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS CF-HQ190L	Same as above
EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS CF-HQ290I	Class IIa	EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS CF-HQ290I	Same as above
EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS CF-HQ290L	Class IIa	EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS CF-HQ290L	Same as above
COLONOVIDEOSCOPE OLYMPUS CF-XZ1200I	Class IIa	COLONOVIDEOSCOPE OLYMPUS CF-XZ1200I	Same as above
COLONOVIDEOSCOPE OLYMPUS CF-XZ1200L	Class IIa	COLONOVIDEOSCOPE OLYMPUS CF-XZ1200L	Same as above
EVIS EXERA III XENON LIGHT SOURCE OLYMPUS CLV-190	Class IIa	EVIS EXERA III XENON LIGHT SOURCE OLYMPUS CLV-190	Same as above
EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500	Class IIa	EVIS X1 VIDEO SYSTEM CENTER OLYMPUS CV-1500	Same as above

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB identification
OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5	Class IIa	OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5	Same as above
OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5A	Class IIa	OES CYSTONEPHROFIBERSCOPE OLYMPUS CYF-5A	Same as above
VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2	Class IIa	VISERA CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF TYPE V2	Same as above
CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VHA	Class IIa	CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VHA	Same as above
CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VHR	Class IIa	CYSTO-NEPHRO VIDEOSCOPE OLYMPUS CYF-VHR	Same as above
SINGLE USE POWERSPIRAL TUBE DPST-1	Class IIa	SINGLE USE POWERSPIRAL TUBE DPST-1	Same as above
RHINO-LARYNGO FIBERSCOPE OLYMPUS ENF-GP2	Class IIa	RHINO-LARYNGO FIBERSCOPE OLYMPUS ENF-GP2	Same as above
RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-V3	Class IIa	RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-V3	Same as above
RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-V4 OLYMPUS ENF-V4	Class IIa	RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-V4 OLYMPUS ENF-V4	Same as above
RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-VH	Class IIa	RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-VH	Same as above
RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-VH2 OLYMPUS ENF-VH2	Class IIa	RHINO-LARYNGO VIDEOSCOPE OLYMPUS ENF-VH2 OLYMPUS ENF-VH2	Same as above
RHINO-LARYNGOFIBERSCOPE OLYMPUS ENF TYPE XP	Class IIa	RHINO-LARYNGOFIBERSCOPE OLYMPUS ENF TYPE XP	Same as above
EVIS EXERA II ULTRASOUND GASTROVIDEOSCOPE OLYMPUS GF TYPE UCT180	Class IIa	EVIS EXERA II ULTRASOUND GASTROVIDEOSCOPE OLYMPUS GF TYPE UCT180	Same as above
EVIS LUCERA ULTRASOUND GASTROVIDEOSCOPE OLYMPUS GF TYPE UCT260	Class IIa	EVIS LUCERA ULTRASOUND GASTROVIDEOSCOPE OLYMPUS GF TYPE UCT260	Same as above
EVIS EUS ULTRASOUND GASTROINTESTINAL VIDEOSCOPE OLYMPUS GF-UE190	Class IIa	EVIS EUS ULTRASOUND GASTROINTESTINAL VIDEOSCOPE OLYMPUS GF-UE190	Same as above

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
EVIS EUS ULTRASOUND GASTROINTESTINAL VIDEOSCOPE OLYMPUS GF-UE290	Class IIa	EVIS EUS ULTRASOUND GASTROINTESTINAL VIDEOSCOPE OLYMPUS GF-UE290	Same as above
EVIS EXERA Ⅲ GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-1TH190	Class IIa	EVIS EXERA Ⅲ GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-1TH190	Same as above
GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-EZ1500	Class IIa	GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-EZ1500	Same as above
GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H170	Class IIa	GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H170	Same as above
EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H185	Class IIa	EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H185	Same as above
EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H190	Class IIa	EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H190	Same as above
EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H190N	Class IIa	EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H190N	Same as above
EVIS LUCERA ELITE GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H290	Class IIa	EVIS LUCERA ELITE GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H290	Same as above
EVIS LUCERA ELITE GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H290EC	Class IIa	EVIS LUCERA ELITE GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H290EC	Same as above
EVIS LUCERA ELITE GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H290T	Class IIa	EVIS LUCERA ELITE GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-H290T	Same as above
EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-HQ190	Class IIa	EVIS EXERA III GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-HQ190	Same as above
EVIS LUCERA ELITE GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-HQ290	Class IIa	EVIS LUCERA ELITE GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-HQ290	Same as above
GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-XP170N	Class IIa	GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-XP170N	Same as above
EVIS LUCERA ELITE GASTROINTESTINAL	Class IIa	EVIS LUCERA ELITE GASTROINTESTINAL	Same as above

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
VIDEOSCOPE OLYMPUS GIF-XP290N		VIDEOSCOPE OLYMPUS GIF-XP290N	
GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-XZ1200	Class IIa	GASTROINTESTINAL VIDEOSCOPE OLYMPUS GIF-XZ1200	Same as above
EVIS LUCERA ELITE PLEURA VIDEOSCOPE OLYMPUS LTF-H290	Class IIa	EVIS LUCERA ELITE PLEURA VIDEOSCOPE OLYMPUS LTF-H290	Same as above
ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-S190-10	Class IIa	ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-S190-10	Same as above
ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-S190-5	Class IIa	ENDOEYE FLEX DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-S190-5	Same as above
ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-S300-10-3D	Class IIa	ENDOEYE FLEX 3D DEFLECTABLE VIDEOSCOPE OLYMPUS LTF-S300-10-3D	Same as above
AIRWAY MOBILESCOPE OLYMPUS MAF-DM2	Class IIa	AIRWAY MOBILESCOPE OLYMPUS MAF-DM2	Same as above
AIRWAY MOBILESCOPE OLYMPUS MAF-GM2	Class IIa	AIRWAY MOBILESCOPE OLYMPUS MAF-GM2	Same as above
AIRWAY MOBILESCOPE OLYMPUS MAF-TM2	Class IIa	AIRWAY MOBILESCOPE OLYMPUS MAF-TM2	Same as above
Lid MAJ-1024	Class IIa	Lid MAJ-1024	Same as above
Lid MAJ-1025	Class IIa	Lid MAJ-1025	Same as above
Container MAJ-1026	Class IIa	Container MAJ-1026	Same as above
O-ring MAJ-1028	Class IIa	O-ring MAJ-1028	Same as above
CYLINDER HOSE FOR UHI-3 MAJ-1080	Class IIa	CYLINDER HOSE FOR UHI-3 MAJ-1080	Same as above
CYLINDER HOSE FOR UHI-3 MAJ-1081	Class IIa	CYLINDER HOSE FOR UHI-3 MAJ-1081	Same as above
CYLINDER HOSE FOR UHI-3 MAJ-1082	Class IIa	CYLINDER HOSE FOR UHI-3 MAJ-1082	Same as above
MEDICAL GAS PIPELINE ADAPTER FOR UHI-3 MAJ-1084	Class IIa	MEDICAL GAS PIPELINE ADAPTER FOR UHI-3 MAJ-1084	Same as above
MEDICAL GAS PIPELINE ADAPTER FOR UHI-3 MAJ-1085	Class IIa	MEDICAL GAS PIPELINE ADAPTER FOR UHI-3 MAJ-1085	Same as above
AIR/WATER VALVE MAJ-1444	Class IIa	AIR/WATER VALVE MAJ-1444	Same as above
PROBE DRIVING UNIT MAJ-1720	Class IIa	PROBE DRIVING UNIT MAJ-1720	Same as above
RESERVOIR TANK MAJ-1727	Class IIa	RESERVOIR TANK MAJ-1727	Same as above
GAS TUBE MAJ-1741	Class IIa	GAS TUBE MAJ-1741	Same as above
LOW FLOW GAS TUBE MAJ-1742	Class IIa	LOW FLOW GAS TUBE MAJ-1742	Same as above

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
EXTRA LOW FLOW GAS TUBE MAJ-1816	Class IIa	EXTRA LOW FLOW GAS TUBE MAJ-1816	Same as above
HAND COIL MAJ-1859	Class IIa	HAND COIL MAJ-1859	Same as above
REFERENCE PLATE MAJ-1860	Class IIa	REFERENCE PLATE MAJ-1860	Same as above
ENDOSCOPE POSITION MARKING PROBE MAJ-1878	Class IIa	ENDOSCOPE POSITION MARKING PROBE MAJ-1878	Same as above
CYLINDER HOSE WITH SWITCH-OVER VALVE (PIN-INDEX) MAJ-1985	Class IIa	CYLINDER HOSE WITH SWITCH-OVER VALVE (PIN-INDEX) MAJ-1985	Same as above
CYLINDER HOSE WITH SWITCH-OVER VALVE (DIN) MAJ-1986	Class IIa	CYLINDER HOSE WITH SWITCH-OVER VALVE (DIN) MAJ-1986	Same as above
GAS/WATER VALVE MAJ-2010	Class IIa	GAS/WATER VALVE MAJ-2010	Same as above
AUXILIARY WATER TUBE MAJ-2021	Class IIa	AUXILIARY WATER TUBE MAJ-2021	Same as above
INSUFFLATION TUBE MAJ-590	Class IIa	INSUFFLATION TUBE MAJ-590	Same as above
AUXILIARY WATER TUBE MAJ-855	Class IIa	AUXILIARY WATER TUBE MAJ-855	Same as above
WATER CONTAINER MAJ-902	Class IIa	WATER CONTAINER MAJ-902	Same as above
Probe/Irrigation Plug MD-807	Class IIa	Probe/Irrigation Plug MD-807	Same as above
AIR/WATER VALVE MH-438	Class IIa	AIR/WATER VALVE MH-438	Same as above
BALLOON CONTROL UNIT OBCU OBCU	Class IIa	BALLOON CONTROL UNIT OBCU OBCU	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190DI	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190DI	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190DL	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190DL	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190TI	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190TI	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190TL	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-H190TL	Same as above
EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS PCF-H290DL	Class IIa	EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS PCF-H290DL	Same as above
EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS PCF-H290TI	Class IIa	EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS PCF-H290TI	Same as above
EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS PCF-H290TL	Class IIa	EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS PCF-H290TL	Same as above

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS PCF-H290ZI	Class IIa	EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS PCF-H290ZI	Same as above
EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS PCF-H290ZL	Class IIa	EVIS LUCERA ELITE COLONOVIDEOSCOPE OLYMPUS PCF-H290ZL	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-HQ190I	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-HQ190I	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-HQ190L	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-HQ190L	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-PH190I	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-PH190I	Same as above
EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-PH190L	Class IIa	EVIS EXERA III COLONOVIDEOSCOPE OLYMPUS PCF-PH190L	Same as above
POWERSPIRAL CONTROL UNIT PSCU	Class IIa	POWERSPIRAL CONTROL UNIT PSCU	Same as above
INTESTINAL VIDEOSCOPE OLYMPUS PSF-1	Class IIa	INTESTINAL VIDEOSCOPE OLYMPUS PSF-1	Same as above
EVIS EXERA III SMALL INTESTINAL VIDEOSCOPE OLYMPUS SIF-H190	Class IIa	EVIS EXERA III SMALL INTESTINAL VIDEOSCOPE OLYMPUS SIF-H190	Same as above
EVIS LUCERA ELITE SMALL INTESTINAL VIDEOSCOPE OLYMPUS SIF-H290S	Class IIa	EVIS LUCERA ELITE SMALL INTESTINAL VIDEOSCOPE OLYMPUS SIF-H290S	Same as above
SINGLE USE SPLINTING TUBE ST-CB1	Class IIa	SINGLE USE SPLINTING TUBE ST-CB1	Same as above
SINGLE USE SPLINTING TUBE ST-SB1	Class IIa	SINGLE USE SPLINTING TUBE ST-SB1	Same as above
EVIS EXERA II ULTRASOUND GASTROVIDEOSCOPE OLYMPUS TGF-UC180J	Class IIa	EVIS EXERA II ULTRASOUND GASTROVIDEOSCOPE OLYMPUS TGF-UC180J	Same as above
DUODENOVIDEOSCOPE OLYMPUS TJF-Q170V	Class IIa	DUODENOVIDEOSCOPE OLYMPUS TJF-Q170V	Same as above
EVIS EXERA III DUODENOVIDEOSCOPE OLYMPUS TJF-Q190V	Class IIa	EVIS EXERA III DUODENOVIDEOSCOPE OLYMPUS TJF-Q190V	Same as above
EVIS LUCERA ELITE DUODENOVIDEOSCOPE OLYMPUS TJF-Q290V	Class IIa	EVIS LUCERA ELITE DUODENOVIDEOSCOPE OLYMPUS TJF-Q290V	Same as above
ENDOSCOPIC CO2 REGULATION UNIT OLYMPUS UCR	Class IIa	ENDOSCOPIC CO2 REGULATION UNIT OLYMPUS UCR	Same as above
ULTRASONIC PROBE UM-3R	Class IIa	ULTRASONIC PROBE UM-3R	Same as above

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
ULTRASONIC PROBE UM-S20-17S	Class IIa	ULTRASONIC PROBE UM-S20-17S	Same as above
ULTRASONIC PROBE UM-S20-20R	Class IIa	ULTRASONIC PROBE UM-S20-20R	Same as above
ENDOSCOPE POSITION DETECTING UNIT UPD-3	Class IIa	ENDOSCOPE POSITION DETECTING UNIT UPD-3	Same as above
URETERO-RENO VIDEOSCOPE OLYMPUS URF-V3	Class IIa	URETERO-RENO VIDEOSCOPE OLYMPUS URF-V3	Same as above
URETERO-RENO VIDEOSCOPE OLYMPUS URF-V3R	Class IIa	URETERO-RENO VIDEOSCOPE OLYMPUS URF-V3R	Same as above
HIGH FLOW INSUFFLATION UNIT UHI-4	Class IIa	HIGH FLOW INSUFFLATION UNIT UHI-4	Same as above
SINGLE USE SUCTION VALVE (Sterile) MAJ-209	Class Is	SINGLE USE SUCTION VALVE (Sterile) MAJ-209	Certificate # DD 60144068 0001 NB # 0197
SINGLE USE BIOPSY VALVE MAJ-210	Class Is	SINGLE USE BIOPSY VALVE MAJ-210	Certificate # DD 60144068 0001 NB # 0197
SINGLE USE BIOPSY VALVE MAJ-1555	Class Is	SINGLE USE BIOPSY VALVE MAJ-1555	Certificate # DD 60144068 0001 NB # 0197
SINGLE USE DISTAL COVER MAJ-2315	Class Is	SINGLE USE DISTAL COVER MAJ-2315	Certificate # DD 60144068 0001 NB # 0197

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/01/23	OMSC_CL607_CL_2024-01-23	Initial issue
2024/04/25	OMSC_CL607_CL_2024-04-25	Revise the letter to be align with OMSC_PLA0_HZ_20240416_EU 2023_607. – to remove EVIS EUS ENDOSCOPIC ULTRASOUND CENTER EU-ME3, HIGH FLOW INSUFFLATION UNIT UHI-5, HEATABLE INSUFFLATION TUBE MAJ-2464, TUBING SET FOR TRANSANAL SURGERY MAJ-2465 and Table 2. – to add HIGH FLOW INSUFFLATION UNIT UHI-4. – Update device name from Single Use Biopsy Forceps FB-456D to ULTRASONIC BIPOLAR GENERATOR USG-410 (EMDN: Z120108) and ULTRASONIC

Date	NB internal reference traceable to each version of the letter	Action
		BIPOLAR GENERATOR USG-410 (EMDN: Z120109). – Update legacy device name from Single Use Biopsy Forceps FB-215U, FB-216U to Single Use Biopsy Forceps FB-215U.
2024/04/30	OMSC_CL607_CL_2024-04-30	Correction made on Table 1 in the previous version. – ULTRASONIC BIPOLAR GENERATOR USG-410 (EMDN: Z120109) – URETERO-RENO FIBERSCOPE URF-P7 – URETERO-RENO FIBERSCOPE URF-P7R

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Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	OLYMPUS MEDICAL SYSTEMS CORP.
Manufacturer address and contact details	2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan Phone: (81) 42-642-21111
Single Registration Number (SRN) (if available)	JP-MF-000008016

Authorised Representative name (if applicable)	Olympus Europa SE & Co. KG
Authorised Representative address and contact details	Wendenstrasse 20, 20097 Hamburg, Germany
Single Registration Number (SRN) (if available)	DE-AR-000006774

Notified body name (if applicable)	TÜV Rheinland LGA Products GmbH
Notified body number (if applicable)	0197
Directive Certificate number(s) to which this confirmation is made (if applicable)	HD 60149405 0001, DD 60144068 0001
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if applicable)	2 November 2022
End date of extended validity/transition period	31 December 2028

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

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We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☐ Expired *before* 20 March 2023: n/a

  ☒ Expired/expires *after* 20 March 2023:

  Choose one applicable statement:

  ☒ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Upclassified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitutes and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

☒ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

- **Quality Management System (QMS)**

  Choose one applicable statement:

  ☐ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

  ☒ A QMS in accordance with Article 10(9) MDR is in place.

  ☒ A notified body has issued the attached certificate for the MDR-compliant QMS.

- **Device(s) as listed in the attached schedule**

  - The device(s) continue to comply with the AIMDD or MDD.
  - There are no significant changes in the design and intended purpose.
  - The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

OLYMPUS MEDICAL SYSTEMS CORP.

2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan

DocuSigned by:
Masaharu Hirose
署名者名: Masaharu Hirose
署名理由: この文書を承認する
署名時刻： 06-6-2024 | 04:03:33 EDT
A80C2ED4CF7A4EA993A0E7A71ACA508A

Signature, Print Name, Title

Contact Details (at least email)

Masaharu Hirose, Vice President of Customer Quality & Management Representative
masaharu.hirose@olympus.com

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Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable) **yyyy-mm-dd**	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period** **yyyy-mm-dd**	**Substitute Device(s)** (if applicable)
B5-2C	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
B7-2C	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
BC-17W	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
BC-201C-1006	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
BC-202D-1210	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
BC-202D-2010	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
BC-202D-3010	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
BC-202D-5010	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

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BC-203D-2006	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
BC-205D-2010	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
BC-V600P-3010	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
BD-210N-0420	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
BD-210N-0440	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
BD-210N-0620	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
BD-210N-0640	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
BD-210N-0830	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
BD-VC431Q-1240-20	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
BD-VC431Q-1240-25	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
BD-VC431Q-1240-30	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
BD-VC431Q-1840-20	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
BD-VC431Q-1840-25	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
BD-VC431Q-1840-30	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

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BF-1TH1100	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
BF-1TH1200	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
BF-1TH190	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
BF-1TQ170	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
BF-H1100	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
BF-H1200	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
BF-H190	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
BF-MP190F	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
BF-MP290F	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
BF-P190	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
BF-P290	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
BF-Q170	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
BF-Q190	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
BF-UC190F	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A

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BF-UC290F	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
BF-XP190	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
BF-XP290	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
BF-XT190	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
BML-610A	DD 60144068 0001	2024-05-26	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
BML-V232QR-26	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
BML-V232QR-30	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
BML-V242QR-30	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
BML-V437QR-30	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
BML-V442QR-30	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
B-V232P-A	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
B-V232P-B	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
B-V233V-A	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
B-V242Q-A	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

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B-V242Q-B	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
B-V432P-A	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
B-V432P-B	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
B-V442Q-A	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
B-V442Q-B	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
CC-220DR	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
CF-EZ1500DI	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
CF-EZ1500DL	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
CF-H170I	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
CF-H170L	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
CF-H185I	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
CF-H185L	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
CF-H190I	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
CF-H190L	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A

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CF-H290ECI	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
CF-H290I	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
CF-H290L	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
CF-HQ1100DI	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
CF-HQ1100DL	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
CF-HQ190I	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
CF-HQ190L	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
CF-HQ290I	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
CF-HQ290L	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
CF-XZ1200I	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
CF-XZ1200L	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
CLV-190	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
CV-1500	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
CV-170	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A

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CYF-5	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
CYF-5A	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
CYF-V2	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
CYF-VH	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
CYF-VHA	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
CYF-VHR	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
D-201-10704	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
D-201-11304	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
D-201-11802	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
D-201-11804	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
D-201-12402	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
D-201-12704	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
D-201-13404	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
D-201-14304	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

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D-201-15004	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
D-201-16403	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
D-206-02	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
D-206-03	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
D-206-04	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
D-206-05	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
D-206-06	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
DPST-1	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
ENF-GP2	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
ENF-V3	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
ENF-V4	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
ENF-VH	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
ENF-VH2	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
ENF-VT3	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A

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ENF-XP	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
FB-210K	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-210U	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-211D	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-211K	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-212U	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-214U	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-215U	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-220K	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-220U	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-221D	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-221K	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-222U	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-224U	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

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FB-225U	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-230K	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-230U	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-231D	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-231K	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-232U	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-234U	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-235U	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-237Z	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-240K	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-240U	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-241D	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-241K	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-242U	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

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FB-244U	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-245U	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-420K	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-433D	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FB-456D	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FD-210U	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FD-230U	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FD-231C	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FD-410LR	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FD-411QR	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FD-411UR	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FD-412LR	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FG-214P	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FG-220P	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

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FG-232L	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FG-244NR	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FG-253SX	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FG-460YR	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FG-51D	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FG-52D	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FG-54D	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FG-55D	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FG-600U	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FG-804L	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FG-V421PR	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FG-V421YR	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FG-V422PR	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FG-V431P	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

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FG-V432P	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FG-V451P	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FS-200L	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
FS-410U	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
GF-UCT180	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
GF-UCT260	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
GF-UE190	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
GF-UE290	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
GIF-1100	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
GIF-1TH190	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
GIF-EZ1500	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
GIF-H170	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
GIF-H185	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
GIF-H190	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A

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GIF-H190N	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
GIF-H290	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
GIF-H290EC	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
GIF-H290T	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
GIF-HQ190	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
GIF-HQ290	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
GIF-XP170N	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
GIF-XP290N	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
GIF-XZ1200	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
HX-201YR-135	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
HX-202LR	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
HX-202UR	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
HX-400U-30	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
HX-610-090	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

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HX-610-090L	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
HX-610-090S	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
HX-610-090SC	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
HX-610-135	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
HX-610-135L	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
HX-610-135S	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
HX-610-135XS	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
HX-810LR	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
HX-810QR	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
HX-810UR	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
K-001	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
K-002	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
K-003	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
K-004	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

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K-005	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
K-006	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
K-007	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
K-008	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
K-009	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
K-010	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
K-011	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
K-012	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
K-401	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
K-402	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
K-403	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
K-404	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-610L	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-611L	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

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KD-612L	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-612U	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-620LR	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-620QR	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-620UR	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-625LR	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-625QR	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-625UR	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-640L	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-645L	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-650L	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-650Q	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-650U	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-655L	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

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KD-655Q	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-655U	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V410V-0720	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V411M-0320	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V411M-0330	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V411M-0720	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V411M-0725	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V411M-0730	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V411M-1520	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V411M-1530	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V411M-3030	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V431M-0720	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V431M-0730	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V440V	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

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KD-V441M	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V451M	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V611M-07201A	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V611M-07201S	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V611M-07202A	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V611M-07202S	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V611M-07251A	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V611M-07251S	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V611M-07252A	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V611M-07252S	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V611M-07301A	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V611M-07301S	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V611M-07302A	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V611M-07302S	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

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KD-V631M-07201A	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V631M-07201S	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V631M-07202A	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V631M-07202S	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V631M-07301A	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V631M-07301S	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V631M-07302A	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-V631M-07302S	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-VC411Q-0320	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-VC411Q-0330	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-VC411Q-0720	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-VC411Q-0730	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-VC412Q-0215	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-VC431Q-0720	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

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KD-VC431Q-0730	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-VC433Q-0720	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-VC433Q-0730	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-VC611Q-07201A	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-VC611Q-07201S	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-VC611Q-07203A	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-VC611Q-07203S	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-VC611Q-07301A	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-VC611Q-07301S	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-VC611Q-07303A	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-VC611Q-07303S	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-VC631Q-07201A	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-VC631Q-07201S	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-VC631Q-07203A	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

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KD-VC631Q-07203S	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-VC631Q-07301A	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-VC631Q-07301S	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-VC631Q-07303A	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
KD-VC631Q-07303S	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
LA-201	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
LA-202	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
LTF-H290	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
LTF-S190-10	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
LTF-S190-5	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
LTF-S300-10-3D	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAF-DM2	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAF-GM2	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAF-TM2	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A

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MAJ-1024	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-1025	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-1026	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-1028	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-1058	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
MAJ-1080	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-1081	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-1082	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-1084	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-1085	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-1351	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
MAJ-1414	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
MAJ-1444	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-1555	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A

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MAJ-1720	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-1727	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-1741	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-1742	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-1816	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-1818	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
MAJ-1819	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
MAJ-1820	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
MAJ-1821	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
MAJ-1859	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-1860	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-1878	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-1985	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-1986	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A

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MAJ-2010	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-2021	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-209	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-2092	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-210	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-2188	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-2189	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-2190	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-2287	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
MAJ-2315	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-233	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
MAJ-249	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
MAJ-590	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-855	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A

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MAJ-901	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MAJ-902	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MD-807	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
MH-438	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
NA-201SX-4021	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NA-201SX-4022	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NA-401D-1321	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NA-401D-1521	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NA-411D-1321	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NA-411D-1521	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NA-421C-1321	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NA-431C-1321	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NA-601D-1519	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NA-U200H-8019	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

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NA-U200H-8019S	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NA-U200H-8022	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NA-U200H-8022S	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NA-U200H-8025	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NA-U201H-8019	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NA-U201H-8022	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NA-U201H-8025	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NA-U401SX-4021	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NA-U401SX-4022	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NA-U401SX-4025N	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-221C-0427	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-400L-0421	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-400L-0423	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-400L-0425	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

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NM-400L-0523	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-400L-0525	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-400L-0621	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-400L-0623	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-400L-0625	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-400U-0323	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-400U-0423	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-400U-0425	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-400U-0523	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-400U-0525	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-400U-0623	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-400U-0625	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-400Y-0423	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-401L-0423	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

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NM-401L-0425	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-401L-0523	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-401L-0525	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-401L-0623	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-401L-0625	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-600L-0421	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-600L-0423	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-600L-0425	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-600L-0521	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-600L-0523	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-600L-0525	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-600L-0621	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-600L-0623	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-600L-0625	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

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NM-610L-0421	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-610L-0423	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-610L-0425	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-610L-0426	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-610L-0521	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-610L-0523	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-610L-0525	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-610L-0621	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-610L-0623	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-610L-0625	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-610U-0323	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-610U-0325	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-610U-0326	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-610U-0423	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

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NM-610U-0425	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-610U-0426	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-610U-0523	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-610U-0525	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-610U-0623	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-610U-0625	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-610U-1825	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
NM-610U-1826	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
OBCU	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
PBD-421-1004	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PBD-421-1005	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PBD-421-1006	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PBD-421-1007	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PBD-421-1008	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

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PBD-421-1009	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PBD-421-1010	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PBD-421-1011	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PBD-421-1012	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PBD-421-1013	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PBD-421-1014	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PBD-421-1015	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PBD-V621R-1005	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PBD-V621R-1007	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PBD-V621R-1009	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PBD-V621R-1012	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PBD-V621R-1015	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PCF-H190DI	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
PCF-H190DL	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A

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PCF-H190TI	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
PCF-H190TL	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
PCF-H290DL	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
PCF-H290TI	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
PCF-H290TL	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
PCF-H290ZI	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
PCF-H290ZL	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
PCF-HQ190I	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
PCF-HQ190L	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
PCF-PH190I	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
PCF-PH190L	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
PR-233Q	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PR-V214Q	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PR-V216Q	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

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PR-V220Q	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PR-V223Q	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PR-V414Q	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PR-V416Q	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PR-V418Q	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PR-V420Q	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PR-V427Q	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PR-V434Q	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PR-V434Y	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PR-V435Q	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PR-V614M	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
PSCU	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
PSF-1	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
PW-205V	DD 60144068 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

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SB-0520FC	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
SB-0535FC	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
SB-0545FC	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
SD-210U-10	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
SD-210U-15	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
SD-210U-25	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
SD-221L-25	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
SD-221U-25	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
SD-230U-20	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
SD-240U-10	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
SD-240U-15	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
SD-240U-25	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
SD-400U-10	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
SD-400U-15	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

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SIF-H190	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
SIF-H290S	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
ST-CB1	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
ST-SB1	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
ST-SB1S	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
TB-0009OF	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
TB-0009OFX	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
TB-0510IC	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
TB-0520FCS	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
TB-0520IC	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
TB-0535FCS	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
TB-0535PC	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
TB-0545FCS	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
TB-0920OE	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A

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TD-SB400	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
TD-TB400	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	BSI Group The Netherlands B.V. No.2797	2028-12-31	N/A
TGF-UC180J	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
TJF-Q170V	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
TJF-Q190V	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
TJF-Q290V	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
UCES-4	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
UCR	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
UHI-4	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
UM-3R-3	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
UM-S20-17S	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
UM-S20-20R-3	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
UPD-3	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
URF-P7	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A

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URF-P7R	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
URF-V3	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
URF-V3R	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A
USG-410	HD 60149405 0001	2022-11-02	TÜV Rheinland LGA Products GmbH No. 0197	TÜV Rheinland LGA Products GmbH No. 0197	2028-12-31	N/A

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Revision history		
Revision:	Description:	Approval date:
0	Initial issue	2024-04-08
1	Added product: BML-V437QR-30	See approval date

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EU-DECLARATION OF CONFORMITY

1. Manufacturer OLYMPUS MEDICAL SYSTEMS CORP.

2951 Ishikawa-cho, Hachioji-shi, Tokyo 192-8507, Japan

Single Registration-No. N/A

2. Article(REF)No. / Article Name Please refer to Attachment 1

3. Product designation Please refer to Attachment 1

4. Serial or Lot No. range Please refer to Attachment 1

5. Product classification Please refer to Attachment 1

6. Authorized representatives in EU

Name Olympus Europa SE & Co. KG

Address Wendenstrasse 20, 20097 Hamburg, Germany *
*Until 31 May 2021 Wendenstrasse 14-18, 20097 Hamburg, Germany

Single Registration-No. TBA

7. Declaration

This declaration was made in sole responsibility of the manufacturer.
The stated product complies with the requirements of following European Directives and Regulations.

The declarations is based on: 93/42/EEC Annex II
2011/65/EU, (EU) 2015/863

8. Notified Body for MDD

Issued by TÜV Rheinland LGA Products GmbH

Address Tillystraße 2, 90431 Nürnberg, Germany

Registration-No. Registration-No.0197

Place, Date: Tokyo, 2021/7/1

Signature:

Director
Product Quality Assurance
Medical Quality Assurance and Regulatory Affairs
Yoshihito Horikawa

ATTACHMENT 1

OLYMPUS

✦The EU-Declaration of Conformity is valid for the following articles:

Product designation	GMDN	EMDN (CND)	Article(REF)No. Article Name	Serial or Lot No. range	UDI-DI	Basic UDI-DI	Classification
GASTROINTESTINAL VIDEOSCOPE	38805	-	OLYMPUS GIF-1100	From 2101046 to	N/A	N/A	Class IIa

✦Applied Standards [RoHS,RED,LVD,EMC]

[RoHS] EN IEC 63000 : 2018

Refer to the Essential Requirements Checklist for above mentioned product. [MDD]

✦Included items

Product designation	Article(REF)No. Article Name
SINGLE USE COMBINATION CLEANING BRUSH	BW-412T
AUXILIARY WATER TUBE	MAJ-855
MOUTHPIECE	MB-142
ETO CAP	MB-156
SUCTION CLEANING ADAPTER	MH-856
CHANNEL PLUG	MH-944
INJECTION TUBE	MH-946
AW CHANNEL CLEANING ADAPTER	MH-948

✦Intended purpose:

This instrument is intended to be used with an Olympus video system center, light source, documentation equipment, monitor, EndoTherapy accessories (such as a biopsy forceps), and other ancillary equipment for endoscopy and endoscopic surgery.

✦Serial or Lot No.

Directive/Regulation	Re-issued DoC-Serial or Lot No. range Starting from	Ended at	New DoC-Serial or Lot No. range Starting from
93/42/EEC	2000251	-	-
2011/65/EU	2000251	2101045	-
2011/65/EU, (EU) 2015/863	-	-	2101046