



EC DECLARATION OF CONFORMITY

(Following the provisions of the Medical Devices Directive 93/42/EEC, Annex II and of the directive 2011/65/EU)

We

Manufacturer
GE Medical Systems Israel, Functional Imaging
4 Hayozma Street,
TIRAT HACARMEL, 30200, Israel

EU Authorized Representative
GE Medical Systems SCS
283 rue de la Minière
78530 BUC, France

Manufacturing site
GE Medical Systems Israel, Functional Imaging
4 Hayozma Street,
TIRAT HACARMEL, 30200, Israel

Declare under our sole responsibility that the device:

Xeleris V Processing & Review System

Workstation, nuclear medicine system

Ref.: Model Configuration Record (PCM) 5848278 and 5866479

UDI-DI code \ Identifier: 00840682147682, 00195278245021

GMDN Code: **40937**


Classification rule (93/42/EC Annex IX): **10 class IIa**

To which this declaration relates, is in conformity with the requirements of the medical devices directive 93/42/EEC which apply to it and with the requirements of the directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

This conformity is based on the following elements:

- For the directive 93/42/EEC (MDD):
 - Technical Documentation/TF Ref./ réf. : DOC2357371 of the product to which this declaration relates.
 - EC certificate: approval of full quality assurance system (Annex II of the directive 93/42 EEC) delivered by **GMED (Notified Body 0459)** / Certificate N° **7927**
 - List of standards applied for CE marking: EN 60601-1:2006 A1:2013 (Clause 14 only), EN 60601-1-6:2010 + A1:2015, EN 62366-1:2015, EN 62304:2006 A1:2015
- For the directive 2011/65/EU (RoHS)
 - Technical Documentation/DHF Ref./ réf: DOC2357371, of the product to which this declaration relates

Tirat Hacarmel
27-Jul-2021


George Mashour
RA Manager, Molecular Imaging

This EC declaration of conformity supersedes the previous declaration dated 15 – Mar – 2021.