



## DECLARATION OF CONFORMITY

Following the provisions of the Medical Devices Directive 93/42/EEC, Annex II

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:

### **NM/CT 860**

Nuclear medicine system, gamma camera, stationary

X-Ray system, Diagnostic, Computed Tomography, Full Body

Ref: Model Configuration Record in PCM 5797110

(ME) Serial Number: **870x64005**

GMDN Code: **40640 & 37618**

UDI-DI code: **00840682140751**

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

Class **IIB**

To which this declaration relates, is in conformity with the requirements of the Medical Devices Directive 93/42/EEC which apply to it.

This conformity is based on the following elements:

- Information included in the documents: Technical Documentation/DHF Ref./ *réf.*: DOC2138563, of the product to which this declaration relates.
- EC certificate: approval of full quality assurance system (Annex II of the Medical Devices Directive 93/42/EEC) delivered by **GMED** (Notified Body 0459) / Certificate N° 7927
- List of harmonized standards applied for CE marking:

EN 60601-1:2006 A1:2013, EN 60601-1-2:2015, EN 60601-1-3:2008 A11:2016, EN 60601-1-6:2010 A1:2015, EN 60601-2-44:2009 A1:2012, EN 62304:2006 A1:2015, EN 62366:2008 A1:2015, EN ISO 10993-1:2009/AC: 2010

Tirat Hacarmel  
15-Nov-2020

  
George Mashour  
RA Manager, Molecular Imaging

This EC declaration of conformity supersedes the previous declaration dated 15-Dec-2019.