



## **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 devices:

**Discovery NM/CT 670 Pro**

**Discovery NM/CT 670 ES**

**Discovery 670 DR**

**NM/CT 870 DR**

Nuclear medicine system, gamma camera, stationary

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

Ref: CT/NM parts identified in Model Configuration Records 5756557, 5767455, 5756559, 5767456, and 5797106

GMDN Code: **40640 & 37618**

UDI-DI code - Discovery NM/CT 670 Pro:	00840682121194, 00840682139373
UDI-DI code - Discovery NM/CT 670 ES:	00840682121187, 00840682123877, 00840682139403
UDI-DI code - Discovery 670 DR:	00840682124393, 00840682139359
UDI-DI code - NM/CT 870 DR:	00840682140836

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:

For the directive 93/42/EEC (MDD):


- Information included in the documents: Technical Documentation/DHF Ref./ réf.: DOC1568678, 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 A2:2016, 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 April 2, 2019.