EC 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 class **IIb** device:

Discovery NM/CT 670

Nuclear medicine system, gamma camera, stationary

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

Ref. : see CT/NM part identified in Model Configuration Record DOC1380949

GMDN Code: **40640 & 37618**

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

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.* : **DOC1084763** , 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 LNE/G-MED (Notified Body 0459) on 26 March 2013 / Certificate N° 7927 rev4 /
- List of harmonized standards applied for CE marking: **EN 60601-1:2006; EN 60601-1-2:2007; EN 60601-1-3:2008; EN 60601-1-6:2010; EN 60601-2-28:2010; EN 60601-2-44:2009; EN 62304:2006; EN 62366:2008; EN 980:2008; EN 1041:2008.**

Tirat Hacarmel,

Huy Doan
Regulatory Affairs Director

05 Aug 2014

This EC declaration of conformity supersedes the previous declaration dated 17 February 2014.