



## **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 **Ila** device:

### **Discovery NM 630**

Nuclear medicine system, gamma camera, stationary

Ref. : see addendum

GMDN Code: **40640**

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.* : **DOC0900686** , 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 rev3 /
- List of harmonized standards applied for CE marking:
  - o EN 60601-1:2006 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
  - o EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests



- 
- EN 60601-1-6:2007 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral Standard: Usability
  - EN 62304:2006 Medical device software - Software life-cycle processes
  - EN 62366:2008 Medical devices - Application of usability engineering to medical devices

Tirat Hacarmel,  
15- October-2013



Huy Doan  
Regulatory Affairs Director

This EC declaration of conformity supersedes the previous declaration dated 11-June-2013.

**ADDENDUM TO THE EC DECLARATION OF CONFORMITY dated 15-Oct-2013**

<b>Product Description</b>	<b>Catalog Designation</b>
<b>Discovery NM 630 System 3/8" Consisting of:</b>	<b>H3100RC</b>
• Discovery 630 NM Gantry	H3100JY
• 3/8" NM Detector	H3100ND
• Discovery 630 IMAGING TABLE	H3100PM
• D630 ACQ PACKAGE	H3100RE
• 17 LCD MILL ACQ MONITOR	H2506KK
• Discovery 630 Installation Kit	H3100RG
<b>Discovery NM 630 System - 5/8" . Consisting of:</b>	<b>H3100RD</b>
• Discovery 630 NM Gantry	H3100JY
• 5/8" NM Detector	H3100PN
• Discovery 630 IMAGING TABLE	H3100PM
• D630 ACQ PACKAGE	H3100RE
• 17 LCD MILL ACQ MONITOR	H2506KK
• Discovery 630 Installation Kit	H3100RG
<b>Accessories</b>	
• D670 PALLET EXTENDER	H3100PG
• MEGP Collimator set(2)W/CART	H2506TC
• LEHR Collimator set(2)W/CART	H2506TB
• D670 ELEGP COLL(2)W/CART	H2506TD
• D670 HEGP COLL(2) W/CART	H2506TE
• D670 PINHOLE (1) W/CART	H2506TF
• D670 FANBEAM (2) W/CART	H2506TG



• D670 LEGP COLL(2) W/CART	H2506TA
• NORAV ECG GATING FOR D630	H2506KR
• Axial Head Holder	H3100NW
• IVY 3000M RWAVE TRIG	H2505JY
• IVY 3000M RWAVE TRIG+REC	H2505JW
• IVY 3000M RWAVE+CART	H2505K
• IVY 3000M RWAVE+REC+CART	H2505KA
• D670 STRAPS&PAD KIT	H3100NP
• R-MADE ARMREST	E8500NA
• FOAM ARMREST	E8500NB
• CONTOURED LEG REST	E8500NC
• UPS & Eaton model 86511	H2506KS
• XELERIS 3 WORKSTATION	H3901KE
• D670 STRAPS&PAD KIT	H3100NP
• D670-D630 Touch Ruler	H3100PS
• 17 LCD MILL ACQ MONITOR	H2506KK
• NM 600 LEUHR collimators	H2401NH
• NM UPS 6 KVA for EMEA except Russia (GEDE LP6 11)	E45051DN
• NM UPS 6 KVA for EMEA only Russia (GEDE LP6 11)	E45051RN
<b>Tools</b>	
• D670 QC POINT SOURCE HLDR	H3100PE
• D670 QC FLOOD SRCHLDR KIT	H3100PF
• NM QA SOURCE HOLDER	H3602SL
• INFINIA BAR PHANTOM	H3602MS
• D670 NM DOLLIES	H3100PB
• D670 QC FLOOD SRCHLDR KIT	H3100PF
• D670-D630 Bar phantom	H3100PL



Options	
• EFB PLANAR LICENSE	H3602NG
• EFB SPECT CAMERA LICENSE	H3602NH
• EFC CAMERA LICENSE	H3602NJ
• EV TOOLKIT LICENSE	H3602NK
• Dynamic SPECT option	H2506TN
• CARD MORPH LICENSE	H3602PT
• D630 TO O640 UPGRADE	H3100ZC
• NM600 DETECTORS DISMOUNT	H2506TR
• NM600 PINHOLE BILATERAL	H2506TL
• NM600 FAST WB SCAN	H2506TM
• D670/D630 OP DCS-ENGLISH	H2506Y
• D670 OP DOCS-DUTCH	H2506WD
• D670-D630 DUTCH DOCS PRINTED	H2507WD
• D670 OP DOCS-FRENCH	H2506WA
• D670-D630 FRENCH DOCS PRINTED	H2507WA
• D670 OP DOCS-GERMAN	H2506WE
• D670-D630 GERMAN DOCS PRINTED	H2507WE
• D670 OP DOCS-ITALIAN	H2506WB
• D670-D630 ITALIAN DOCS PRINTED	H2507WB
• NM 600 Russian DOC	H2506WR
• NM 600 RUSSIAN DOC PR	H2507WR
• OP docs Romanian	H2506XC
• NM 600 ROMANIAN DOC PR	H2507YC
• NM600 OP DOCs Swedish	H2506WH
• NM600 Swedish DOC PRINTED	H2507WH
• NM600 OP DOCs Estonian	H2506WN



• NM600 Estonian DOC PRINTED	H2507WN
• NM600 OP DOCs Hungarian	H2506XA
• NM600 Hungarian DOC PRINTED	H2507YA
• NM600 OP DOCs Bulgarian	H2506XB
• NM600 Bulgarian DOC PRINTED	H2507YB
• NM600 DANISH DOC PRINTED	H2507WM
• D670 OP DOCS-DANISH	H2506WM
• NM 600 FINNISH DOCS	H2506WG
• NM 600 FINNISH DOC PR	H2507WG
• NM 600 Polish DOC	H2506WL
• NM 600 POLISH DOC PR	H2507WL
• NM 600 PORTUGUESE	H2506WK
• NM 600 PORTUGUESE DOC PR	H2507WK
• NM 600 NORWEGIAN DOC	H2506WJ
• NM 600 NORWEGIAN DOC PR	H2507WJ
• NM 600 Spanish DOC	H2506WC
• NM 600 Spanish DOC PR	H2507WC
• NM 600 Czech DOC	H2506WP
• NM 600 Czech DOC PR	H2507WP
• NM600 Greek OP Docs	H2506WY
• NM600 Greek Doc PR	H2507WY