GE Healthcare

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 HANGWEI MEDICAL SYSTEMS CO., LTD.
West Area of Building No.3, No.1 Yongchang North Road,
Beijing Economic and Technological Development Area,
BEIJING 100176 CHINA

EU Authorized Representative

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

Manufacturing site

Site	Products being manufactured
GE HANGWEI MEDICAL SYSTEMS CO., LTD. **West Area of Building No.3, No.1 Yongchang North Road,** **Beijing Economic and Technological Development Area,** **BEIJING 100176 CHINA**	**Discovery CT590 RT, Optima CT580, Discovery RT**
GE Medical Systems, LLC **3000 North Grandview Blvd** **Waukesha, WI 53188 USA**	**Discovery CT590 RT, Optima CT580, Discovery RT**

Declare under our sole responsibility that the device:

Discovery CT590 RT, Optima CT580, Discovery RT

X ray system, diagnostic, computed tomography, full body

Ref.: see CT parts identified in Model Configuration Record 5490950PCM, 5726796PCM, **5726796-2PCM**

GMDN Code: **37618**

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 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)
  1. Technical Documentation/DHF Ref./ réf: **DOC0843074**, of the product to which this declaration relates
  2. EC certificate: approval of full quality assurance system (Annex II of the directive 93/42 EEC) delivered by **G-MED (Notified Body n°0459)** Certificate N° 7848
  3. harmonized standards applied on the product to which this declaration relates
- For the directive 2011/65/EU (RoHS)
  1. Technical Documentation/DHF Ref./ réf: **DOC0843074**, of the product to which this declaration relates
- Digitally signed by Chicu Natalia
  Date: 2022.01.25 12:52:35 EET
  Reason: MoldSign Signature
  Location: Moldova

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- List of harmonized standards applied for CE marking:

Discovery CT590 RT and Optima CT580:
EN 60601-1:2006 /A1:2013, EN 60601-1-2:2007/AC:2010, EN 60601-1-6:2010, EN 60601-1-3: 2008/AC: 2010, EN 60601-2-44:2009, EN 62304:2006/AC:2008, EN 62366:2008, EN ISO 10993-1:2009/AC:2010

Discovery RT:

EN 60601-1:2006 /A1:2013, EN 60601-1-2:2007/AC:2010, EN 60601-1-6:2010, EN 60601-1-3: 2008/AC: 2010, EN 60601-2-44:2009+A1:2012, EN 62304:2006/AC:2008, EN 62366:2008, EN ISO 10993-1:2009/AC:2010.

Wang Xing

Beijing,
Nov 9, 2018

Wang Xing
Regulatory Affairs Manager

This EC declaration of conformity supersedes the previous declaration dated May 4, 2018.

Released