



EC 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 Healthcare Japan Corporation
7-127, Asahigaoka 4-chome, Hino-shi, Tokyo
191-8503 Japan

EU Authorized Representative

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

Manufacturing site

GE Healthcare Japan Corporation
7-127, Asahigaoka 4-chome, Hino-shi, Tokyo
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GE Medical Systems, LLC

3000N. Grandview Blvd, Waukesha,
WI, 53188 USA

GE Hangwei Medical Systems Co., Ltd.

West Area of Building No.3, No.1 Yongchang North Road, Beijing Economic and Development
Area, Beijing 100176 China

Declare under our sole responsibility that the device:

Revolution EVO

<X-ray system, diagnostic, computed tomography, full body >

Ref.: Revolution EVO CT system Product Configuration Master

5463926-31PCM, 5463926-32PCM, 5463926-33PCM, 5463926-34PCM

GMDN Code: **37618**

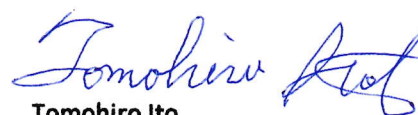
Classification rule (93/42/EC Annex IX) : **Rule 10 Class IIb**

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 or state of the art substances in electrical and electronic equipment.

This conformity is based on the following elements:

- For the directive 93/42/EEC (MDD)
 - Technical Documentation/DHF Ref./ réf.: **DOC1732895** 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 G-MED (Notified Body No. 0459) / Certificate N°7834
 - Harmonized standards applied on the product to which this declaration relates
- For the directive 2011/65/EU (RoHS)
 - Technical Documentation/DHF Ref./ réf.: **DOC1732895**, of the product to which this declaration relates

Tokyo, 17 March 2020


Tomohiro Ito
Sr. Regulatory Affairs Leader

This EC declaration of conformity supersedes the previous declaration dated **6 February 2020**.



ADDENDUM TO THE DECLARATION OF CONFORMITY DOC1568331

Harmonized Standards	
EN 60601-1:2006/A1:2013	EN 60601-2-44:2009/A2:2016
EN 60601-1-2:2015	EN 62304:2006/AC:2008
EN 60601-1-3:2008/A11:2016	EN 62366-1:2015
EN 60601-1-6:2010/A1:2015	EN ISO 10993-1: 2009/AC:2010