



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

**Datex-Ohmeda, Inc.
3030 Ohmeda Drive
PO Box 7550
Madison, WI 53707-7550 USA**

EU Authorized Representative

**GE Medical Systems SCS
283 rue de la Minière
78530 BUC, France
FI-00510**

Manufacturing Site

**Datex-Ohmeda, Inc.
3030 Ohmeda Drive
P.O. Box 7550
Madison, WI 53707-7550 USA**

Manufacturing Site

**GE Medical Systems (China) Co., Ltd
19 Changjiang Road
Wuxi Jiangsu, PR China 214028**

Declare under our sole responsibility that the class IIb device:

CARESCAPE R860 and its accessories

Ref: **1506-8600-000**

GMDN Code: **42411** UMDNS Code: **17-429**

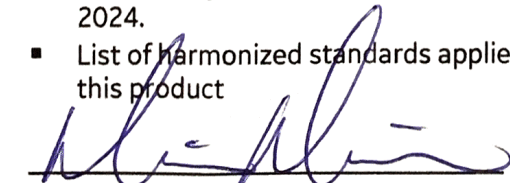
Classification rule (93/42/EC Annex IX): **Class IIb, Rule 9 and Rule 12**

UDI-ID: **00840682102346**

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 (as assessed by the manufacturer).

This conformity is based on the following elements:

- Information included in the Technical Documentation DOC1546200 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 TÜV Rheinland LGA Products GmbH, Tillystraße 2, 90431, Nuremberg, Germany, Notified Body #0197, Certificate N° HD 2222912-1, until 26 May 2024.
- List of harmonized standards applied for CE marking is in the technical documentation file for this product



Monica Morrison
Executive, Regulatory Affairs

23 JUN 2021

Washington, DC, USA

This EC declaration of conformity supersedes the previous declaration dated 16 June 2021. Page 1
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DOC1546262

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