



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