GE Healthcare

Datex·Ohmeda

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
P.O. Box 7550
Madison, WI 53707-7550
USA

EU Authorized Representative

GE Healthcare Finland Oy
Kuortaneenkatu 2
Helsinki, Finland
FI-00510

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**

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 60109676 0001, issued 26 April 2016 and valid until 19 April 2021.
- List of harmonized standards applied for CE marking is in the technical documentation file for this product

Monica Morrison
Regulatory Affairs Director

4 MAY 2016
Madison, WI USA

This EC declaration of conformity supersedes the previous declaration dated 8 January 2015.