



## 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**

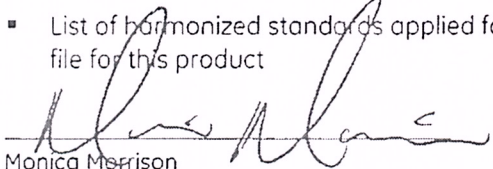
GMDN Code: **42411** UMDNS Code: **17-429**

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

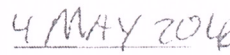
To which this declaration relates, is in conformity with the requirements of the medical devices directive 93/42/EEC which apply to it and with the requirements of the directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (as assessed 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

  
Madison, WI USA

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

