



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.
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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**

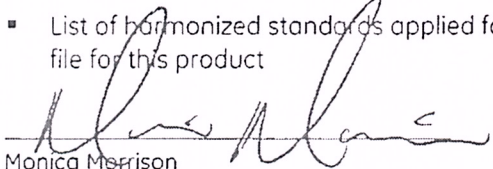
GMDN Code: **42411** UMDNS Code: **17-429**

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

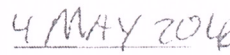
To which this declaration relates, is in conformity with the requirements of the medical devices directive 93/42/EEC which apply to it and with the requirements of the directive 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment (as assessed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

