GE Healthcare

Datex-Ohmeda

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

Digitally signed by Chicu Natalia
Date: 2024.06.05 15:51:50 EEST
Reason: MoldSign Signature
Location: Moldova

Declare under our sole responsibility that the class IIb device:

Aestiva/5 7900
Or **Aestiva/5**
Or **Aestiva S/5**
Or **Aestiva 3000**

Ref: 1006-9305-000

GMDN Code: 37710, UMDNS Code: 10-134

Classification rule (93/42/EC Annex IX): Class IIb, Rule 11

To which this declaration relates is in conformity with the requirements of the medical devices directive 93/42/EEC which apply to it. In addition, the product is in conformity 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 documents:
  Technical Documentation of the product to which this declaration relates is maintained at Datex-Ohmeda, Inc.
- 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 60098566 0001 valid until 9 June 2016.
- List of harmonized standards applied for CE marking is located in the Technical Documentation file for this product.

Monica Morrison
Regulatory Affairs Manager

14 JAN 2015
Madison, USA, Day Month -Year

This EC declaration of conformity supersedes the previous declaration dated 1 July 2014.

Reference of the Declaration: DOC1015236