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: 2024.06.03 15:51:48 EEST
Reason: Moldsign Signature
Location: Moldova

Declare under our sole responsibility that the class IIb device:

Aespire 7900

Ref: 1009-9012-000

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: DOC1015160