



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
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EU Authorized Representative
GE Healthcare Finland Oy
Kuortaneenkatu 2
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Manufacturing Site
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Manufacturing Site
Datex-Ohmeda, Inc.
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Declare under our sole responsibility that the class IIb devices:

Carestation 650

Version: A1 REF: 1012-9650-000

Carestation 650c

Version: A1 REF: 1012-9655-000

Carestation 620

Version: A1 REF: 1012-9620-000

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 Ref: DOC1659791, 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 60144148 0001 valid until 27 May 2024.
- List of harmonized standards applied for CE marking is located in the Technical Documentation file for this product.


Monica Morrison
Regulatory Affairs Director

27 NOV 2019
Madison, USA, Day Month -Year