



EU DECLARATION OF CONFORMITY

Following the provisions of the medical devices regulation 2017/745.

Following the provisions of the RoHS directive 2011/65/EU, Articles 7, 13 and Annex VI.

We:

Manufacturer

GE Healthcare Finland Oy
Kuortaneenkatu 2
FI-00510 Helsinki
Finland

Single Registration Number (SRN):
FI-MF-000001176

Manufacturing Site

Technical Services for Electronics, Inc.
2F, No. 21 Jiankang Rd., Jhongha Dist.,
New Taipei City 235, Taiwan, R.O.C.

Declare under our sole responsibility that the device:

Trunk Cables

Basic UDI-DI:

Invasive Blood Pressure Trunk Cables: 8406821BUG00043GW

Temperature Trunk Cables: 8406821BUG00044GY

Cardiac Output Trunk Cables: 8406821BUG00045H2

Identification number: See Appendix 1

Intended Purpose:

Invasive Blood Pressure Trunk (IBP) Cables

The invasive blood pressure cables are intended to be used for connecting one or two invasive blood pressure transducers to GE monitoring equipment requiring rectangular 11-pin connector cable.

Temperature Trunk Cables

The temperature cables are intended to be used for connecting one or two reusable or disposable temperature probes to GE monitoring equipment requiring a rectangular 11-pin connector cable.



Cardiac Output Trunk Cables

The reusable cardiac output cables are intended to be used for connecting a cardiac output catheter to GE monitoring equipment requiring a rectangular 11-pin connector cable.

GMDN Code and Description:

47487 for Trunk Cables, Electrical-only medical device connection cable, reusable

EMDN Code and Description:

Z1203020280, Multi-parameter monitors – hardware accessories

Class: I

Classification rule (Annex VIII): 1

To which this declaration relates is in conformity with the requirements of the medical devices regulation 2017/745 that apply to it and with the requirements of the RoHS directive 2011/65/EU, article 4 on the restriction of the use of certain hazardous substances in electrical and electronic equipment.

This conformity is based on the following elements:

- Technical Documentation reference: DOC2359950, of the product to which this declaration relates.
- MDSAP and ISO13485:2016: Approval of Quality Management System delivered by DQS Medizinprodukte GmbH, Germany/ Certificate Unique ID 170771008
- The list of standards applied is located in the Technical File for this product.

SIGNATURE:

Date of issue: 06-May-2022
Place of issue: Helsinki
Name: Rauno Ruoho
Function: Regulatory Affairs Director

This EC Declaration of Conformity supersedes the previous dated 16-July-2021 and applies to revisions listed in Appendix 1 or previous revision if the product includes MD-symbol label.