EU DECLARATION OF CONFORMITY

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

Following the provisions of the RoHS directive 2011/65/EU.

We:

Legal Manufacturer	EU Authorized Representative
GE Medical Systems Information Technologies, Inc. 9900 Innovation Drive Wauwatosa, WI 53226 USA **Single Registration Number (SRN):** US-MF-000017529	GE Medical Systems SCS 283 rue de la Minière 78530 BUC, France **Single Registration Number (SRN):** FR-AR-000000344

Manufacturing Sites

GE Medical Systems Information Technologies –
Critikon de Mexico S. de R.L. de C.V.
Calle Valle Del Cedro 1551
Juarez 32575 Chihuahua Mexico

Declare under our sole responsibility that the device:

DURA-CUF®
Non-Invasive Blood Pressure Cuffs

Basic UDI-DI:
8406821BUG00036GZ

Identification number:
See Appendix 1

SIGNATURE: Date: 2022.03.04 14:30:42 +01'00'

Date of Issue:	04-March-2022
Place of Issue:	Wauwatosa, WI, USA
Name:	William Jung
Function:	Regulatory Affairs Director – Monitoring Solutions

This Declaration of Conformity relating to Technical Documentation DOC2374213 supersedes the previous Declaration signed 01-December-2021.

Reference of the Declaration: DOC2374217

Intended Purpose:
GE CRITIKON blood pressure cuffs are accessories used in conjunction with noninvasive blood pressure (NIBP) measurement systems. SOFT-CUF and CLASSIC-CUF cuffs and inflation systems are non-sterile and limited reuse (may be single-patient use or optional limited reuse). They are available in neonatal, pediatric and adult sizes. DURA-CUF and inflation systems are non-sterile and may be reused. They are available in pediatric and adult sizes. The devices are not designed, sold or intended for use except as indicated.

GMDN Code and Description:
34978 – Cuff, blood pressure, reusable
EMDN Code and Description:
Z12040180 – GENERAL MEDICINE INSTRUMENTS FOR DIAGNOSIS AND MONITORING - HARDWARE

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 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: DOC2374213, of the product to which this declaration relates.
- ISO 13485:2016: Approval of Quality Management System delivered by TÜV Rheinland, Germany/ Certificate N SX 60146867 0001

SIGNATURE: Date: 2022.03.04 14:31:11 +01'00'

Date of Issue:	04-March-2022
Place of Issue:	Wauwatosa, WI, USA
Name:	William Jung
Function:	Regulatory Affairs Director – Monitoring Solutions

This Declaration of Conformity relating to Technical Documentation DOC2374213 supersedes the previous Declaration signed 01-December-2021.

Appendix 1 – List of part numbers

Part Number	Rev	Description
DUR-A2-2A-L-5S	2	DURA-CUF, ADULT LONG, , 23 - 33 CM, 80369-5, 5/ BOX
DUR-A2-2A-5S	2	DURA-CUF, ADULT, , 23 - 33 CM, 80369-5, 5/ BOX
DUR-P2-2A-5S	2	DURA-CUF, CHILD, , 12 - 19 CM, 80369-5, 5/ BOX
DUR-P1-2A-5S	2	DURA-CUF, INFANT, , 08 - 13 CM, 80369-5, 5/ BOX
DUR-A3-2A-L-5S	2	DURA-CUF, LARGE ADULT LONG, , 31 - 40 CM, 80369-5, 5/ BOX
DUR-A3-2A-5S	2	DURA-CUF, LARGE ADULT, , 31 - 40 CM, 80369-5, 5/ BOX
DUR-A1-2A-L-5S	2	DURA-CUF, SMALL ADULT LONG, , 17 - 25 CM, 80369-5, 5/ BOX
DUR-A1-2A-5S	2	DURA-CUF, SMALL ADULT, , 17 - 25 CM, 80369-5, 5/ BOX
DUR-T1-2A-5S	2	DURA-CUF, THIGH, , 38 - 50 CM, 80369-5, 5/ BOX
002130	ZAA	DURA-CUF, ADULT LONG, 1 TB , 23 - 33 CM, 5/ BOX
002131	V	DURA-CUF, LARGE ADULT LONG, 1 TB , 31 - 40 CM, 5/ BOX
002274	N	DURA-CUF, INFANT, 1 TB , 08 - 13 CM, 5/ BOX
002275	U	DURA-CUF, CHILD, 1 TB , 12 - 19 CM, 5/ BOX
002276	V	DURA-CUF, SMALL ADULT, 1 TB , 17 - 25 CM, 5/ BOX
002277	ZAB	DURA-CUF, ADULT, 1 TB , 23 - 33 CM, 5/ BOX
002278	V	DURA-CUF, LARGE ADULT, 1 TB , 31 - 40 CM, 5/ BOX
002279	V	DURA-CUF, THIGH, 1 TB , 38 - 50 CM, 5/ BOX
2059301-504	2	PACK DURA-CUF VARIOUS 2T , 80369-5, 6/ PK
2059301-503	2	PACK DURA-CUF ADULT 2T , 80369-5, 6/ PK
2059301-502	2	PACK DURA-CUF PEDIATRIC 2T , 80369-5, 6/ PK
2059301-501	2	PACK DURA-CUF ADULT 2T CLICK, 80369-5, 3/ PK

End of Document

SIGNATURE: Date: 2022.03.04 14:31:31 +01'00'

Date of Issue: 04-March-2022
Place of Issue: Wauwatosa, WI, USA
Name: William Jung
Function: Regulatory Affairs Director – Monitoring Solutions

This Declaration of Conformity relating to Technical Documentation DOC2374213 supersedes the previous Declaration signed 01-December-2021.

Reference of the Declaration: DOC2374217