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
Wipro GE Healthcare Private Limited
No: 4 Kadugodi Industrial Area
Bangalore 560067 Karnataka INDIA

EU Authorized Representative
GE Medical systems SCS
283 rue de la Minière
78530 BUC, FRANCE

Manufacturing site

Wipro GE Healthcare Private Limited
No: 4 Kadugodi Industrial Area
Bangalore 560067 Karnataka INDIA

Declare under our sole responsibility that:

Corometrics 170 Series Fetal Monitor and its accessories

Reference: see addendum

GMDN Code: 37796

has been assigned to Class IIb : Classification rule (93/42/EC Annex IX) : **Rule 10**

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 File: DOC0471286 , of the product to which this declaration relates.

- ISO 13485 Certificate: Approval of Quality Assurance System delivered by GMED France / Certificate N° 15813, CE 7651

- CE Certification delivered by **GMED France** / Certificate N° CE 21266

- List of harmonized standards applied for CE marking is located in the Technical Documentation for this product.

- The Medical Device bears the mark **CE0459**

Monica Morrison, Regulatory Affairs Manager **Date:** 12 SEP 2014

The technical documentation is filed at Wipro GE Healthcare Private Limited

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ADDENDUM TO THE EC DECLARATION OF CONFORMITY

Name	Part Number
CORO 171 Series	2000268-196
CORO 172 Series	2000268-197
CORO 173 Series	2001972-049
CORO 174 Series	2001972-050
CORO 174 Series	2001972-053

Accessories

Item	Part or Catalog Number	Class (Annex IX Rule)
General Supplies		
Remote Event Marker	3919BAO	I (1) All non-invasive devices are in Class I,
Ultrasound Transducer		Active devices intended for diagnosis are in Class IIa: - if they are intended to supply energy which will be absorbed by the human body, except for devices used to illuminate the patient's body, in the visible spectrum,
Loop-Style Ultrasound Transducer 8-foot Cord	5700LAX	IIa (10)
Button-Style Ultrasound Transducer, 8-foot Cord	5700HAX	IIa (10)
Button-Style Ultrasound Transducer, 10-foot Cord	5700JAX	IIa (10)
Ultrasound Transducer, Button-Style, 5 foot cord	5700GAX	IIa (10)
Ultrasound Transducer, Loop-Style, 5 foot cord	5700KAX	IIa (10)
Ultrasound Transducer, Loop-style, 10 Foot cord	5700MAX	IIa (10)
Belts		Non-invasive devices so in Class I
Reusable Belt for Loop-Style Transducer, Mesh Style (10/carton)	4425AAO	I (1)
Reusable Belt for Loop-Style Transducer, Velcro Style (10/carton)	4425CAO	I (1)
Semi-Reusable Belt for Loop-Style Transducer, Velcro Style (2/pack; 50 packs/carton)	4425FAO	I (1)
Single-Patient Use Belt for Loop-Style Transducer, Foam Style with Velcro Closure	8024AAO	I (1)
Reusable Belt for Button-Style Transducer, Blue (10/carton)	2015827-001	I (1)
Belt Reuse Button Blue 2/PACK 100/CASE (1 pink	2015919-001	I (1)

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Item	Part or Catalog Number	Class (Annex IX Rule)
and 1 blue/pack) (100 packs/case)		
FECG		Non-invasive devices so in Class I
Legplate for Qwik Connect Plus Spiral Electrode, 8-foot Cord	1590AAO	I (1)
Legplate for Qwik Connect Plus Spiral Electrode, 8-foot Cord	1591AAO	I (1)
Tocotransducer		Active disgnostic device are in Class I
Loop-Style Tocotransducer 8-foot Cord	2264LAX	I (12)
Button-Style Tocotransducer 8-foot Cord	2264HAX	I (12)
Tocotransducer, Button-top, 5 Foot cord	2264GAX	I (12)
Tocotransducer, Button-top, 10' cord	2264JAX	I (12)
Tocotransducer, Loop-style, 10 foot cord	2264MAX	I (12)
Tocotransducer, Loop-top, 5 foot cord	2264KAX	I (12)
Cart		All non-invasive devices are in Class I,
GCX CART- COMPATIBLE FOR MOUNTING CORO 170 SERIES MONITORS	2076563-001	I (1)

12 SEP 2014

Monica Morrison, Regulatory Affairs Manager **Date:**

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

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