DECLARATION OF CONFORMITY

CE 0123

Ref., No : MS220509HR02DOC

We <TRISMED CO., LTD.> herewith declare that the below mentioned products meet the provisions of the Council Directive 93/42/EEC amended by MDD 2007/47/EC for medical devices. All supporting documentation is retained under of the manufacture. We are exclusively responsible for the declaration of conformity.

The Manufacturer has adress the following:

TRISMED CO., LTD

409 SMECA, 65 Techno 3-ro, Yuseong-gu, Daejeon 34016, Republic of Korea

The Manufacturer has designed the following authorized representative within the European Market:

OBELIS SA

Bd. Général Wahis 53-1030 Brussels-Belgium

Phone: 32.2.732.59.54, Fax: 32.2.732.60.03, E-mail: mail@obelis.net

Devices Covered by the Declaration of Conformity

Product name	Fetal Monitor
Commercial name	FM8000 (type: FM8010, FM8007)
Catalogue number	MD-Cat8000-001
Classification	Class IIa following Rule 10 of Annex IX of the Directive 93/42/EEC
Serial number	

Detail of NB:

TÜV SÜD Product Service GmbH Ridlerstraße 65, 80339 München Germany.

CE Certificate:

EC Certificate No. : G1 050166 0025 Rev.00

Valid from 2019-11-19, Valid until 2023-08-26

Conformity assessment route:

Annex II(excluding section 4) of MDD 93/42/EEC amended by MDD 2007/47/EC

Standards: Refer to the Technical File

Issue place and date : Daejeon, 2022-05-09

Hoon-kyeu Lee, Ph.D./Representative