EU Declaration of Conformity

Product Name:	Fetal Monitoring System
Model Name:	FC1400
Accessories:	UC Probe, US Probe, Event Marker
Intended purpose:	FC1400 detects and displays single or twins Fetal Heart Rate (FHR), Fetal Movement (FM), and Uterine Activity (UA) in real-time, and also provides the fetal heartbeat sound with internal speaker.
GMDN Code:	43958
EMDN Code:	Z12080101
Classification:	Class IIb (Rule 10 according to EU MDR ANNEX VIII)
Conformity Assessment Procedure:	Annex IX of Regulation (EU) 2017/745
Basic UDI-DI:	880927694FC14LB
Applied standards:	Refer to Annex I

We hereby declare under our sole responsibility, that the product above is in compliance with the applicable MDR Regulation (EU) 2017/745 requirements. It is subject to the conformity assessment procedures set out in Annex IX of the MDR Regulation (EU) 2017/745 based on the quality management system and on the assessment of technical documentation.

Manufacturer:	Bionet Co., Ltd.
Address:	5F, 61 Digital-ro 31-gil, Guro-gu, Seoul 08375, REPUBLIC OF KOREA
SRN:	KR-MF-000013439
EU Representative:	CMC Medical Devices & Drugs S.L.
Address:	C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain
SRN:	ES-AR-000000293
Notified Body:	3EC International a.s
Address:	Hraničná 18, 821 05 Bratislava, Slovak Republic
Notified Body No:	2265
Certificate No:	2025-MDR/QS-017
Place, Date of Declaration:	Seoul, 2025-04-17
Name/Position:	Minn Steven Sangwon, Chief Executive Officer

Annex I: Applied list of standards

Common specifications

There is no common specification for the device.

Harmonized standards

No.	Standard	Description
1	EN ISO 14971:2019	Medical devices - Application of risk management to medical devices
2	EN ISO 13485:2016/A11:2021	Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)
3	EN ISO 10993-10:2023	Biological evaluation of medical devices - Part 10: Tests for skin sensitization (ISO 10993-10:2021)
4	EN ISO 10993-23:2021	Biological evaluation of medical devices - Part 23: Tests for irritation (ISO 10993-23:2021)
5	EN ISO 15223-1:2021	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied -Part 1: General requirements

Other standards

No.	Standard	Description
1	EN 60601-1:2006/A2:2021 (IEC 60601-1:2005+AMD1:2012+AMD2:2020)	Medical electrical equipment Part 1: General requirement for basic safety and essential performance
2	EN 60601-1-2:2015/A1:2021 (IEC 60601-1-2:2014/A1:2020)	Medical electrical equipment Part1-2: General requirements Section1.2 Collateral standard: Electromagnetic compatibility
3	EN 60601-1-6:2010/A2:2021 (EC 60601-1-6:2010/A2:2020)	Medical electrical equipment Part 1-6: General requirements for safety – Collateral standard: Usability
4	EN 60601-1-8:2013/A2:2021 (IEC 60601-1-6:2006/AMD2:2020)	Medical device – Part 1-8: General requirements for safety collateral standard: General requirements, tests, and guidance for alarm systems in medical electrical equipment and medical electrical systems
5	EN 60601-2-37:2008/A11:2011 (IEC 60601-2-37:2007+AMD1:2015)	Medical electrical equipment -- Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment
6	EN 62304:2006/A1:2015 (IEC 62304:2006/A1:2015)	Medical device software life-cycle process
7	EN ISO 20417:2021	Medical devices - Information to be supplied by the manufacturer
8	EN 62366-1:2015/A1:2020 (IEC 62366-1:2015/A1:2020)	Medical device - Application of usability engineering to medical devices
9	EN ISO 10993-1:2020	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process
10	EN ISO 10993-5:2009	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)

Other solutions applied

No.	Standard	Description
1	MDCG 2020-5	Clinical Evaluation - Equivalence
2	MDCG 2020-7	Post-market clinical follow-up (PMCF) Plan Template
3	MDCG 2022-21	Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745
4	MEDDEV 2.7/1 rev.4	Clinical evaluation: Guide for manufacturers and notified bodies
5	MEDDEV 2.12/1 rev.8	Guidelines on a Medical Devices Vigilance System