

We, the following manufacturer is sole responsible for this declaration:

Manufacturer Address	Bionet Co., Ltd. 5F, 61 Digital-ro 31-gil Guro-gu, Seoul 08375, REPUBLIC OF KOREA	
European	CMC Medical Devices & Drugs S.L.	
Representative	C/ Horacio Lengo № 18, CP 29006, Málaga, Spain	
Product Categories	Accessories of Bionet Products	
Model Name	# Attachment	
Classification (MDD, Annex IX)	IIa (Rule 10)	
Conformity Assessment Route	Annex.II excluding 4	

We here with declare that the above-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.

Standards

Notified Body

All applied harmonized Standards were adopted (published in the Official Journal of the European Communities) TÜV SÜD Product Service GmbH, Ridlerstr. 65, D-80339 München, Germany

CE 0123

Identification No.: (EC) CERTIFICATE: Issue Date of CE cert. Valid until Place, Date of Declaration

No.: G1 046135 0044 Rev.00 March 24. 2021 May 26. 2024 Seoul, July 01, 2021

Name Position MINN STEVEN SANGWON Chief Executive Officer



Attachment

	Item code [Part No.]	Description
Fetal Monitor Accessories	130201-000600	DOPPLER TRANSDUCER
	130201-000701	UC/TOCO TRANSDUCER
	130201-000700	UC/TOCO TRANSDUCER
	130202-000600	DOPPLER TRANSDUCER 1 MHz
	130202-000700	TOCO TRANSDUCER
	130215-000900	FC1400 DOPPLER TRANSDUCER
	130215-000800	FC1400 TOCO TRANSDUCER