

File No.	BN-DOC-Sono
Rev No.	6
Rev. Date	2023.11.01
Page No.	1 / 1

EU Declaration of Conformity

Product Categories:	Handheld Ultrasound Scanners
Brand(Model Name):	SonoMe (5C, 10L, 14L, 5CB, 10LB, H5C10L, H5C, H10L) SONOFINDER (SF14L25)
Intended purpose:	The devices is a handheld ultrasound scanner, designed to obtain and examine ultrasound images, measure anatomical structures, and analyze body fluids that are to be used with a software application on a mobile phone or tablet.
GMDN Code:	60924
UMDN Code:	Z11040106
Classification:	Class IIa (Rule 10 according to EU MDR ANNEX VIII)
Conformity Assessment Procedure:	Annex IX of Regulation (EU) 2017/745
Basic UDI-DI:	880927694USSMWP

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.

We also declare under our sole responsibility, that the product above is in conformity with the relevant requirements of Radio Equipment Directive 2014/53/EU.

EN ISO 15223-1:2021	EN ISO 20417:2021	EN ISO 13485:2016/A11:2021
EN ISO 10993-1:2020	EN ISO 10993-5:2009	EN ISO 10993-10:2023
EN ISO 10993-23:2021	EN ISO 14971:2019	EN 60601-1:2006/A2:2021
EN 60601-1-2:2015/A1:2021	EN 60601-2-37:2008/A11:2011	EN 60601-1-6:2010/A2:2021
EN 62304:2006/A1:2015	EN 62366-1:2015/A1:2020	ETSI EN 301 489-1 V2.2.3 (2019-11)
ETSI EN 301 489-17 V3.2.4 (2020-09)	ETSI EN 300 328 V2.2.2 (2019-07)	EN 62311:2020

Manufacturer:	Bionet Co., Ltd.
Address:	5F, 61 Digital-ro 31-gil Guro-gu, Seoul 08375, REPUBLIC OF KOREA
SRN:	KR-MF-000013439
Website:	www.sonome.com(SonoMe), www.nfinders.com(SONOFINDER)

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:	CE 2265

Certificate No: 2023-MDR/QS-030

Place, Date of Declaration: Seoul, 2023.11.01

Name/Position: Jongju Na, Chief Executive Officer

