EU Declaration of Conformity

In accordance with Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017

We herewith declare that the under-mentioned products meet the provisions of the Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017. This EU Declaration of Conformity is issued under the sole responsibility of the manufacturer. All supporting documentation is retained under the premises of the manufacturer. The device that is covered by the present declaration is in conformity with the Regulation (EU) 2017/745.

Product Name	SpO2 Sensor Probe
Model Name	WA-1XX (X) , WA -1XX - X (X) *Refer to Annex I of this document*
Product Description	Monitoring devices of a vital physiological parameter is designed to function the same as the compatible original equipment manufacturer (OEM) Pulse Oximeter Sensor. The sensor utilizes IR LED sources respectively along with a silicon photodiode detector to detect changes in oxygen saturation in the blood. The oxygen saturated blood absorbs different amounts of light at each wavelength (red and infrared) as compared with unsaturated blood, the amount of light absorbed at each wavelength by the blood in each pulse can be used to calculate oxygen saturation.
Intended Purpose	SpO2 Sensor Probe is indicated for non-invasive spot-checking and/or continuous monitoring of adult patients who are well or poorly perfused, during both motion and non-motion conditions. It is intended for use in environments including the operating room, surgical recovery, critical care, emergency room, long-term care, and mobile environments.
GMDN Code	37808
GMDN Term Name	Pulse oximeter probe, reusable
GMDN Definition	A photoelectric device designed to be applied externally to a body site (e.g., fingertip, ear lobe, bridge of nose, toe, or bridge of the foot) for the transcutaneous measurement of haemoglobin oxygen saturation (SpO2) in arterial blood using signals produced by a light-emitting diode (LED) and received by a photodetector. The signals are subsequently transmitted to an oximeter/monitor (not included) which measures and displays the SpO2. This is a reusable device

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Basic UDI-DI of the device	**8800179300008ZV**
Risk Class of the device	**Class IIb** In accordance with the Rule 10 of Classification Rules set out in Annex VIII of Regulation (EU) 2017/745
Harmonised Standards	*Refer to Annex II of this document*
Manufacturer	**MEDNIS CO.,Ltd.** B-414, 119, Gasan digital 1-ro, Geumcheon-gu, Seoul, Republic of Korea
Single Registration Number	KR-MF-000024165
Authorised Representative	**CMC Medical Devices & Drugs S.L.** C/Horacio Lengo Nº 18 CP 29006, Málaga-Spain TEL:+34951214054 FAX:+34952330100 Email: info@cmcmedicaldevices.com
Single Registration Number	ES-AR-000000293
Notified Body	**3EC International a.s.** **Notified Body number: 2265** 3EC International a.s. Hranicna 18 Bratislava 82105 SLOVAKIA Bratislava 82105 Country: Slovakia Phone: +421 2 58318343 Fax: +421 2 58318345 Email: info@3ec.sk Website: www.3ec.sk
Conformity Assessment Procedure	Part A of Annex XI of Regulation (EU) 2017/745
Identification of the certificate issued	EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-005 by 3EC International a.s.
Date of issuance	31.01.2024

Date: 26 Feb 2024

Place of issue: Gyeonggi-do, Republic of Korea

Gyeung_sig Yang ,
The president of the manufacturer

Annex I

No.	Type	Model Name	Connector type
1	**WA-100**	WA-100(B6M114)	D-SUB
2		WA-100(LDAS520B)	
3		WA-100-1(B6M114)	USB
4		WA-100-1(LDAS520B)	
5		WA-100-2(B6M114)	MINIDIN
6		WA-100-2(LDAS520B)	
7		WA-100-3(B6M114)	MDHP-7P
8		WA-100-3(LDAS520B)	
9		WA-100-4(B6M114)	MODULA JACK
10		WA-100-4(LDAS520B)	
11		WA-100-5(B6M114)	NEMOSA, FG CONNECTOR
12		WA-100-5(LDAS520B)	
13		WA-100-6(B6M114)	51004-6P
14		WA-100-6(LDAS520B)	
15		WA-100-7(B6M114)	MINIDIN-6P
16		WA-100-7(LDAS520B)	
17		WA-100-8(B6M114)	BCI
18		WA-100-8(LDAS520B)	
19		WA-100-9(B6M114)	B-TYPE
20		WA-100-9(LDAS520B)	
21		WA-100-10(B6M114)	NOVA MATRIX
22		WA-100-10(LDAS520B)	
23		WA-100-11(B6M114)	MDC-6P
24		WA-100-11(LDAS520B)	
25		WA-100-12(B6M114)	14P CONNECTOR
26		WA-100-12(LDAS520B)	
27	**WA-101**	WA-101(B6M114)	D-SUB / 152600-003400
28		WA-101(LDAS520B)	
29		WA-101-1(B6M114)	MDH-12P
30		WA-101-1(LDAS520B)	
31		WA-101-2(B6M114)	MDK-10P
32		WA-101-2(LDAS520B)	
33		WA-101-3(B6M114)	MDD-10P
34		WA-101-3(LDAS520B)	
35		WA-101-4(B6M114)	MDK D-SUB
36		WA-101-4(LDAS520B)	
37		WA-101-5(B6M114)	Omeda
38		WA-101-5(LDAS520B)	
39		WA-101-6(B6M114)	Nemosa FG
40		WA-101-6(LDAS520B)	
41		WA-101-7(B6M114)	MDC-6P
42		WA-101-7(LDAS520B)	
43		WA-101-8(B6M114)	Phone jack 7P
44		WA-101-8(LDAS520B)	
45		WA-101-9(B6M114)	D-SUB Volt
46		WA-101-9(LDAS520B)	
47		WA-101-10(B6M114)	MDS CONNECTOR
48		WA-101-10(LDAS520B)	
49		WA-101-11(B6M114)	USB
50		WA-101-11(LDAS520B)	
51		WA-101-12(B6M114)	MDH-8P
52		WA-101-12(LDAS520B)	
53		WA-101-13(B6M114)	MINIDIN 7P

54		WA-101-13(LDAS520B)	
55		WA-101-14(B6M114)	BCI
56		WA-101-14(LDAS520B)	
57		WA-101-15(B6M114)	14P CONNECTOR
58		WA-101-15(LDAS520B)	
59		WA-101-16(B6M114)	D-SUB (WHITE)
60		WA-101-16(LDAS520B)	
61		WA-101-17(B6M114)	NOVA MATRIX
62		WA-101-17(LDAS520B)	
63	**WA-102**	WA-102(B6M114)	D-SUB
64		WA-102(LDAS520B)	
65		WA-102-1(B6M114)	MDH-12P
66		WA-102-1(LDAS520B)	
67		WA-102-2(B6M114)	MDK-10P
68		WA-102-2(LDAS520B)	
69		WA-102-3(B6M114)	MDD-10P
70		WA-102-3(LDAS520B)	
71	**WA-103**	WA-103(B6M114)	D-SUB
72		WA-103(LDAS520B)	
73		WA-103-1(B6M114)	MDH-12P
74		WA-103-1(LDAS520B)	
75		WA-103-2(B6M114)	MDK-10P
76		WA-103-2(LDAS520B)	
77		WA-103-3(B6M114)	MDD-10P
78		WA-103-3(LDAS520B)	
79		WA-103-4(B6M114)	MINIDIN 7P
80		WA-103-4(LDAS520B)	
81		WA-103-5(B6M114)	MDC-7P
82		WA-103-5(LDAS520B)	
83		WA-103-6(B6M114)	BCI
84		WA-103-6(LDAS520B)	
85		WA-103-7(B6M114)	D-SUB
86		WA-103-7(LDAS520B)	
87	**WA-104**	WA-104(B6M114)	D-SUB
88		WA-104(LDAS520B)	
89		WA-104-1(B6M114)	MDD-10P
90		WA-104-1(LDAS520B)	
91		WA-104-2(B6M114)	MDK-10P
92		WA-104-2(LDAS520B)	
93		WA-104-3(B6M114)	MDH-12P
94		WA-104-3(LDAS520B)	
95		WA-104-4(B6M114)	MDK D-SUB
96		WA-104-4(LDAS520B)	
97		WA-104-5(B6M114)	MDH-8P New type
98		WA-104-5(LDAS520B)	
99		WA-104-6(B6M114)	BCI
100		WA-104-6(LDAS520B)	
101		WA-104-7(B6M114)	MINI USB
102		WA-104-7(LDAS520B)	
103	**WA-108**	WA-108(B6M114)	D-SUB
104		WA-108(LDAS520B)	
105	**WA-109**	WA-109(B6M114)	D-SUB / 152600-031400
106		WA-109(LDAS520B)	
107	**WA-110**	WA-110(B6M114)	D-SUB
108		WA-110(LDAS520B)	
109	**WA-112**	WA-112(B6M114)	D-SUB
110		WA-112(LDAS520B)	

Annex II

1. Harmonised Standards

No.	Standard	Standard Title	Source
1	**EN ISO 13485:2016**	Medical devices – Quality management systems – Requirements for regulzatory purposes (ISO 13485:2016) EN ISO 13485:2016/AC:2018 EN ISO 13485:2016/A11:2021	COMMISSION IMPLEMENTING DECISION (EU) 2022/757 of 11 May 2022
2	**EN ISO 14971:2019**	Medical devices – Application of risk management to medical devices (ISO 14971:2019) EN ISO 14971:2019/A11:2021	COMMISSION IMPLEMENTING DECISION (EU) 2022/757 of 11 May 2022
3	**EN ISO 14155:2020**	Clinical investigation of medical devices for human subjects - Good clinical practice (ISO 14155:2020)	COMMISSION IMPLEMENTING DECISION (EU) 2021/610 of 14 April 2021
4	**EN ISO 15223-1:2021**	Medical devices - Symbols to be used with information to be supplied by the manufacturer - Part 1: General requirements (ISO 15223-1:2021)	COMMISSION IMPLEMENTING DECISION (EU) 2022/6 of 4 January 2022
5	**EN 60601-1-6:2010/A2:2021**	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability (IEC 60601-1-6:2010)	STANDARDS CENCENELEC.EU
6	**EN 62366-1:2015**	Medical devices - Part 1: Application of usability engineering to medical device	STANDARDS CENCENELEC.EU
7	**EN ISO 10993-5:2009**	Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity (ISO 10993-5:2009)	STANDARDS CENCENELEC.EU

2. Applied standards other than the harmonised standards

No.	Standard	Title of standard
1	**IEC 60601-1:2005+AMD1:2012+AMD2:2020** **(IEC 60601-1:2022 SER)**	Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
2	**IEC 62471:2006**	Photobiological safety of lamps and lamp systems
3	**ISO 80601-2-61:2017**	Medical electrical equipment — Part 2-61: Particular requirements for basic safety and essential performance of pulse oximeter equipment
4	**ISO 10993-10:2021**	Biological evaluation of medical devices — Part 10: Tests for skin sensitization
5	**ISO 10993-23:2021**	Biological Evaluation Of Medical Devices - Part 23: Tests For Irritation
6	**ISO 20417:2021**	Medical devices — Information to be supplied by the manufacturer