



3EC International a.s., Hraničná 18, 821 05 Bratislava, Slovak Republic
Notified body No. 2265

EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-005

MEDNIS CO., Ltd.

B-414, 119, Gasan digital 1-ro, Geumcheon-gu, Seoul, 08589, Republic of Korea

SRN No.: KR-MF-000024165

Name of the Authorized representative:

CMC Medical Devices & Drugs S.L., C/Horacio Lengo N° 18 CP 29006, Málaga-Spain

This EU Quality Management System Certificate issued in accordance with the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended confirms, that quality management system of medical device:

SpO2 Sensor Probe

Model name: WA-1XX (X) , WA -1XX - X (X)

(for detailed list refer to Annex I)

Intended purpose: See Annex II

MD class IIb, Rule 10

(detailed list is stated in the annex(es) if applicable)

meets the requirements on quality management system according to the Chapter I and III of Annex IX of the Regulation (EU) 2017/745 of the European Parliament and of the Council on medical devices as amended.

Conditions for or limitations to the validity of the certificate: N/A

Validity of the certificate is conditional upon positive results of regular surveillance audits.

Notified body No. 2265 has performed assessment of the quality management system of the abovementioned medical device and found that it meets the requirements stated above. The outcome of the assessment of the quality management system of the abovementioned medical device is stated in the MD Technical Documentation Assessment Report No. MDR066_2022 from 22.08.2023, MD Clinical Evaluation Report No. MDR066_2022 from 25.09.2023 and MD Audit Report No. MDR066_2022 from 10.01.2024. Information on all examinations and tests performed is stated in the abovementioned reports and is available on request.

This **EU Quality Management System Certificate** applies only to the quality management system of the abovementioned medical device. The certificate validity is conditional upon fulfilment of relevant legal requirements by the manufacturer.



Valid from: **31.01.2024**
Valid until: **31.01.2029**
First issue: **31.01.2024**
Revision: **00**
History: **See Annex III**

In Bratislava, Slovakia, 31.01.2024



3EC International a.s.
Katarína Tomin Srdošová, PhD.
Director of NB2265



ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-005

issued for the company

MEDNIS CO., Ltd.

B-414, 119, Gasan digital 1-ro, Geumcheon-gu, Seoul, 08589, Republic of Korea

List of medical devices covered by the EU Quality Management System Certificate:

Type	Model Name	Connector type
WA-100	WA-100(B6M114)	D-SUB
	WA-100(LDAS520B)	
	WA-100-1(B6M114)	USB
	WA-100-1(LDAS520B)	
	WA-100-2(B6M114)	MINIDIN
	WA-100-2(LDAS520B)	
	WA-100-3(B6M114)	MDHP-7P
	WA-100-3(LDAS520B)	
	WA-100-4(B6M114)	MODULA JACK
	WA-100-4(LDAS520B)	
	WA-100-5(B6M114)	NEMOSA, FG CONNECTOR
	WA-100-5(LDAS520B)	
	WA-100-6(B6M114)	51004-6P
	WA-100-6(LDAS520B)	
	WA-100-7(B6M114)	MINIDIN-6P
	WA-100-7(LDAS520B)	
	WA-100-8(B6M114)	BCI
	WA-100-8(LDAS520B)	
	WA-100-9(B6M114)	B-TYPE
	WA-100-9(LDAS520B)	
	WA-100-10(B6M114)	NOVA MATRIX
	WA-100-10(LDAS520B)	
	WA-100-11(B6M114)	MDC-6P
	WA-100-11(LDAS520B)	
	WA-100-12(B6M114)	14P CONNECTOR
	WA-100-12(LDAS520B)	

Page 1 of 7



In Bratislava, Slovakia, 31.01.2024
Valid until 31.01.2029



Katarína Tomin Srdosová, PhD.
Director of NB2265



ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-005

issued for the company

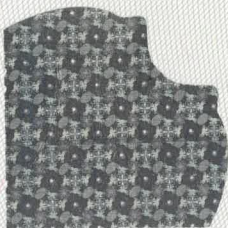
MEDNIS CO., Ltd.

B-414, 119, Gasan digital 1-ro, Geumcheon-gu, Seoul, 08589, Republic of Korea

List of medical devices covered by the EU Quality Management System Certificate:

Type	Model Name	Connector type
WA-101	WA-101(B6M114)	D-SUB
	WA-101(LDAS520B)	
	WA-101-1(B6M114)	MDH-12P
	WA-101-1(LDAS520B)	
	WA-101-2(B6M114)	MDK-10P
	WA-101-2(LDAS520B)	
	WA-101-3(B6M114)	MDD-10P
	WA-101-3(LDAS520B)	
	WA-101-4(B6M114)	MDK D-SUB
	WA-101-4(LDAS520B)	
	WA-101-5(B6M114)	Omeda
	WA-101-5(LDAS520B)	
	WA-101-6(B6M114)	Nemosa FG
	WA-101-6(LDAS520B)	
	WA-101-7(B6M114)	MDC-6P
	WA-101-7(LDAS520B)	
	WA-101-8(B6M114)	Phone jack 7P
	WA-101-8(LDAS520B)	
	WA-101-9(B6M114)	D-SUB Volt
	WA-101-9(LDAS520B)	
	WA-101-10(B6M114)	MDS CONNECTOR
	WA-101-10(LDAS520B)	
	WA-101-11(B6M114)	USB
	WA-101-11(LDAS520B)	
	WA-101-12(B6M114)	MDH-8P
	WA-101-12(LDAS520B)	

Page 2 of 7



In Bratislava, Slovakia, 31.01.2024
Valid until 31.01.2029



Katarína Tomin Srdošová, PhD.
Director of NB2265



ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-005

issued for the company

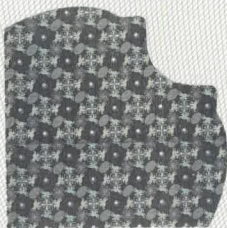
MEDNIS CO., Ltd.

B-414, 119, Gasan digital 1-ro, Geumcheon-gu, Seoul, 08589, Republic of Korea

List of medical devices covered by the EU Quality Management System Certificate:

Type	Model Name	Connector type
WA-101	WA-101-13(B6M114)	MINIDIN 7P
	WA-101-13(LDAS520B)	
	WA-101-14(B6M114)	BCI
	WA-101-14(LDAS520B)	
	WA-101-15(B6M114)	14P CONNECTOR
	WA-101-15(LDAS520B)	
	WA-101-16(B6M114)	D-SUB (WHITE)
	WA-101-16(LDAS520B)	
	WA-101-17(B6M114)	NOVA MATRIX
	WA-101-17(LDAS520B)	
WA-102	WA-102(B6M114)	D-SUB
	WA-102(LDAS520B)	
	WA-102-1(B6M114)	MDH-12P
	WA-102-1(LDAS520B)	
	WA-102-2(B6M114)	MDK-10P
	WA-102-2(LDAS520B)	
	WA-102-3(B6M114)	MDD-10P
	WA-102-3(LDAS520B)	
WA-103	WA-103(B6M114)	D-SUB
	WA-103(LDAS520B)	
	WA-103-1(B6M114)	MDH-12P
	WA-103-1(LDAS520B)	
	WA-103-2(B6M114)	MDK-10P
	WA-103-2(LDAS520B)	
	WA-103-3(B6M114)	MDD-10P
	WA-103-3(LDAS520B)	

Page 3 of 7



In Bratislava, Slovakia, 31.01.2024
Valid until 31.01.2029



Katarina Tomin Srdošová, PhD.
Director of NB2265



ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-005

issued for the company

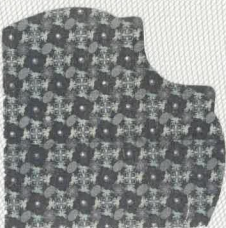
MEDNIS CO., Ltd.

B-414, 119, Gasan digital 1-ro, Geumcheon-gu, Seoul, 08589, Republic of Korea

List of medical devices covered by the EU Quality Management System Certificate:

Type	Model Name	Connector type
WA-103	WA-103-4(B6M114)	MINIDIN 7P
	WA-103-4(LDAS520B)	
	WA-103-5(B6M114)	MDC-7P
	WA-103-5(LDAS520B)	
	WA-103-6(B6M114)	BCI
	WA-103-6(LDAS520B)	
	WA-103-7(B6M114)	D-SUB
	WA-103-7(LDAS520B)	
WA-104	WA-104(B6M114)	D-SUB
	WA-104(LDAS520B)	
	WA-104-1(B6M114)	MDD-10P
	WA-104-1(LDAS520B)	
	WA-104-2(B6M114)	MDK-10P
	WA-104-2(LDAS520B)	
	WA-104-3(B6M114)	MDH-12P
	WA-104-3(LDAS520B)	
	WA-104-4(B6M114)	MDK D-SUB
	WA-104-4(LDAS520B)	
	WA-104-5(B6M114)	MDH-8P New type
	WA-104-5(LDAS520B)	
	WA-104-6(B6M114)	BCI
	WA-104-6(LDAS520B)	
	WA-104-7(B6M114)	MINI USB
	WA-104-7(LDAS520B)	

Page 4 of 7




Katarina Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 31.01.2024
Valid until 31.01.2029



ANNEX I TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-005

issued for the company

MEDNIS CO., Ltd.

B-414, 119, Gasan digital 1-ro, Geumcheon-gu, Seoul, 08589, Republic of Korea

List of medical devices covered by the EU Quality Management System Certificate:

Type	Model Name	Connector type
WA-108	WA-108(B6M114)	D-SUB
	WA-108(LDAS520B)	
WA-109	WA-109(B6M114)	D-SUB
	WA-109(LDAS520B)	
WA-110	WA-110(B6M114)	D-SUB
	WA-110(LDAS520B)	
WA-112	WA-112(B6M114)	D-SUB
	WA-112(LDAS520B)	

Page 5 of 7




Katarina Tomin Srdošová, PhD.
Director of NB2265

In Bratislava, Slovakia, 31.01.2024
Valid until 31.01.2029



ANNEX II TO EU QUALITY MANAGEMENT SYSTEM CERTIFICATE No. 2024-MDR/QS-005

issued for the company

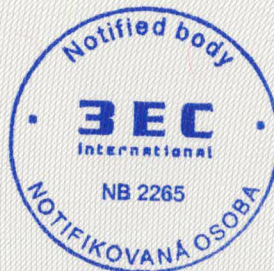
MEDNIS CO., Ltd.

B-414, 119, Gasan digital 1-ro, Geumcheon-gu, Seoul, 08589, Republic of Korea

Intended purpose of medical devices covered by the EU Quality Management System Certificate:

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.

Page 6 of 7



In Bratislava, Slovakia, 31.01.2024
Valid until 31.01.2029


Katarína Tomin Srdošová, PhD.
Director of NB2265



**ANNEX III TO EU QUALITY MANAGEMENT SYSTEM
CERTIFICATE No. 2024-MDR/QS-005**

issued for the company

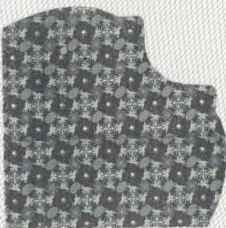
MEDNIS CO., Ltd.

B-414, 119, Gasan digital 1-ro, Geumcheon-gu, Seoul, 08589, Republic of Korea

Certificate history:

Revision	EU QMS Certificate reference	Date of issue	Application for Conformity Assessment of MD number	Description
00	2024-MDR/QS-005	31.01.2024	MDR066_2022	Initially granted certification

Page 7 of 7



In Bratislava, Slovakia, 31.01.2024
Valid until 31.01.2029

Katarina Tomin Srdošova, PhD.
Director of NB2265