

Document Title:	EC DECLARATION OF CONFORMITY			
Document No:	NV_01-00-16	Revision: 11	Date: 10.02.2021	Page: 1 of 3

We, the

Norav Medical GmbH

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SRN: **DE-MF-000006715**

hereby declare under our sole responsibility that the Medical Devices specified on page 2, which are cables and leads that are connected to our products for *Cardio-Pulmonary Diagnostics* are in conformity with **Annex I** (*General safety and performance requirements*) of the *Regulation (EU) 2017/745 (MDR)*. The Medical Devices listed on page 2 have been classified to be **Class I** devices according to the MDR Classification Rules of **Annex VIII, Rule 1** which is:

“All non-invasive devices are classified as class I, unless one of the rules set out hereinafter applies.”

The devices are marked accordingly with

CE

The Norav Medical GmbH has implemented and maintains a Quality Management System in accordance with the provisions of the **EN ISO 13485:2016, amended by A11/2021**. This declaration is supported by the *Quality Management System approval* for which we have appointed the Certification Body

BSI – British Standard Institution

Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands

The following standards apply to the devices:

EN ISO 13485:2016 (amended by A11:2021)	<i>Medical devices – Quality Management Systems – Requirements for regulatory purposes.</i>
EN ISO 15223-1:2021	<i>Medical devices – Symbols to be used with MD labels, labelling and information to be supplied.</i>
EN ISO 14971:2019-12	<i>Medical devices – Application of risk management to medical devices.</i>
EN ISO 24971:2020	<i>Medical Devices — Guidance on the Application of ISO 14971</i>
ANSI/AAMI EC53:2013	<i>ECG Trunk Cables and Patient Lead Wires.</i>
2011/65/EU	<i>Directive of the European Council on the restriction of the use of certain hazardous substances in Electrical and Electronic Equipment (RoHS II)</i>

The Applicable Codes and Terms are:

GMDN: 35748	<i>Cable / Lead</i>	Global Location No.:	4260498560004
UMDNS: 15754	<i>Cables / Leads, ECG</i>	Basic UDI-DI No.:	426049856DE55252NMCBLTD

Authorised Signatory:

Willi Schlosser

Name

20.05.2025, Mainz-Kastel

Date (dd.mm.yyyy) Place

Quality Affairs Manager

Position

Signature

NORAV Medical GmbH
Christof-Ruthof-Weg 10
55252 Mainz-Kastel
Tel: 06134/567983-0
Fax: 06134/567983-14

Catalogue No.	UDI-DI No.	Catalogue No.	UDI-DI No.	Catalogue No.	UDI-DI No.
C3-C-E-ODU	04260498564293	C7-S-E-EI	04260498563920	C10-S-E-D-08	04260498568086
C3-C-U-ODU	04260498564309	C7-S-U-EI	04260498563913	C10-S-U-D-08	04260498568093
C3-C-E-ODU-07	04260498566211	C7-S-E-EI-07	04260498567768	C10-S-E-D-10K-03	04260498564019
C3-C-U-ODU-07	04260498567812	C7-S-U-EI-07	04260498567775	C10-S-U-D-10K-03	04260498564026
C3-C-E-ODU-08	04260498566372	C7-S-E-EI-08	04260498567270	C10-S-E-EI	04260498563968
C3-C-U-ODU-08	04260498566389	C7-S-U-EI-08	04260498567041	C10-S-U-EI	04260498563951
C3-C-E-ODU-1K	04260498565962	-----	-----	C10-S-E-EI-07	04260498567751
C3-C-U-ODU-1K	04260498565979	C10-B-E-D-02	04260498561742	C10-S-U-EI-07	04260498567744
C3-C-E-ODU-1K-08	04260498568024	C10-B-U-D-02	04260498561759	C10-S-E-EI-08	04260498567072
C3-C-U-ODU-1K-08	04260498568031	C10-B-U-D-03	04260498562268	C10-S-U-EI-08	04260498567089
C3-C-LL-ODU-V	04260498566105	C10-B-E-D-04	04260498560509	-----	-----
C3-C-U-LL-D	04260498563074	C10-B-U-D-04	04260498560516	L3D-C-U-ODU	04260498566037
C3-C-U-LL-D-08	04260498568062	C10-B-E-D-06	04260498566143	L3-S-MF-NRP-1-08	04260498567980
C3-C-U-LL-D4R	04260498566112	C10-B-E-D-10K-03	04260498564040	-----	-----
C3-C-U-LL-D-FU	04260498566792	C10-B-U-D-10K-03	04260498564033	L10-B-E-W	04260498562572
C3-C-U-LL-I-D	04260498566167	C10-B-E-D-M	04260498562251	L10-C-E-W-02	04260498562589
C3-C-U-LL-LA-D4R	04260498566075	C10-B-U-D-M	04260498562275	L10-C-U-W-02	04260498562602
C3-C-U-LL-LA-D4R-08	04260498568079	C10-B-E-EI	04260498563982	L10-C-E-W-07	04260498567799
C3-C-U-LL-ODUR	04260498565948	C10-B-U-EI	04260498563975	L10-C-U-W-07	04260498567805
C3-C-U-LL-ODUR-08	04260498568055	C10-B-E-EI-07	04260498566280	L10-C-E-W-08	04260498567102
C3-C-U-LL-ODUR-FU	04260498566136	C10-B-U-EI-07	04260498566297	L10-C-U-W-08	04260498567119
C3-C-U-LL-ODUR-W	04260498565993	C10-B-E-ODU	04260498563050	L10-C-E-W-L-02	04260498564101
C3-ODU-EX	04260498565955	C10-B-U-ODU	04260498563067	L10-C-U-W-L-02	04260498564118
C3-ODU-EX-08	04260498568048	C10-B-E-TEI-08	04260498567713	L10-C-E-W-L1-07	04260498566983
C3-ODU-EX-FU	04260498565863	C10-B-U-TEI-08	04260498567720	L10-C-U-W-L1-07	04260498566990
C3-ODU-EX-V	04260498566006	C10-C-E-D-02	04260498561766	L10-S-E-W-02	04260498562619
C3-S-U-EI	04260498563876	C10-C-U-D-02	04260498562299	L10-S-U-W-02	04260498562626
C3-S-U-EI-07	04260498567898	C10-C-E-D-04	04260498560523	L10-S-E-W-07	04260498567911
C3-S-U-EI-08	04260498567010	C10-C-U-D-04	04260498560530	L10-S-U-W-07	04260498567850
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C4-C-E-EI-07	04260498567843	C10-C-U-D-08	04260498567171	L10-S-U-W-08	04260498567133
C4-C-U-EI-07	04260498567836	C10-C-E-D-10K-03	04260498564057	L10-S-E-W-L-02	04260498563906
C4-C-E-EI-08	04260498567195	C10-C-U-D-10K-03	04260498564064	L10-S-U-W-L-02	04260498564071
C4-C-U-EI-08	04260498567188	C10-C-E-EI-07	04260498567867	L10-S-E-W- L1-07	04260498566976
C4-C-E-ODU	04260498566044	C10-C-U-EI-07	04260498567874	L10-S-U-W-L1-07	04260498566969
C4-C-U-ODU	04260498566051	C10-C-E-EI-08	04260498567225	-----	-----
C4-S-U-D4R	04260498566068	C10-C-U-EI-08	04260498567232	LC1-C-E-W-07	04260498566785
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C5-C-E-EI-07	04260498567034	C10-C-U-ODU	04260498562305	LC2-C-E-W-07	04260498566396
C5-C-U-EI-07	04260498567027	C10-D-C-U-D	04260498561735	LC2-S-E-W-07	04260498566402
C5-C-E-EI-08	04260498567218	C10-S-E-D-02	04260498561773	LC3-C-E-W-07	04260498566419
C5-C-U-EI-08	04260498567201	C10-S-U-D-02	04260498561780	LC3-S-E-W-07	04260498566426
C5-S-U-EI	04260498563890	C10-S-E-D-03	04260498562312	LC4-C-E-W-07	04260498566433
C5-S-U-EI-07	04260498567829	C10-S-E-D-04	04260498560547	LC4-S-E-W-07	04260498566440
C5-S-U-EI-08	04260498567263	C10-S-U-D-04	04260498560554		

Catalogue No.	UDI-DI No.	Catalogue No.	UDI-DI No.	Catalogue No.	UDI-DI No.
LC5-C-E-W-07	04260498566457	LRA-C-U-W-07	04260498566617	C-USB-AB (MINI)3	04260498562398
LC5-S-E-W-07	04260498566464	LRA-S-U-W-07	04260498566624	C-USB-AB0.5	04260498562381
LC6-C-E-W-07	04260498566471	LLL-C-U-W-07	04260498566556	C-USB-AB2	04260498562404
LC6-S-E-W-07	04260498566488	LLL-S-U-W-07	04260498566563	C-USB-AB3	04260498562411
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LV1-C-U-W-07	04260498566655	LRL-S-U-W-07	04260498566648	C-USB-EXT	04260498562435
LV1-S-U-W-07	04260498566662	-----	-----	-----	-----
LV2-C-U-W-07	04260498566679	C-DL800-PC5-3	04260498565870	C-LIMB-CLAMPS-AD-01	04260498560981
LV2-S-U-W-07	04260498566686	C-DL800-PC7-3	04260498565887	C-LIMB-CLAMPS-P-01	04260498560998
LV3-C-U-W-07	04260498566693	C-DL900-PC-5-3	04260498565894	C-SUCTION-ELECTRODE-01	04260498561032
LV3-S-U-W-07	04260498566709	C-DL900-PC7-3	04260498565900	C-LIMB-CLAMPS-AD-08	04260498568161
LV4-C-U-W-07	04260498566716	C-DL900-USB	04260498565917	C-LIMB-CLAMPS-P-08	04260498568178
LV4-S-U-W-07	04260498566723	-----	-----	C-SUCTION-ELECTRODE-08	04260498568482
LV5-C-U-W-07	04260498566730	C-NBP-232	04260498565924	-----	-----
LV5-S-U-W-07	04260498566747	C-NBP-USB	04260498561728	C-ADAPT-BANANA-SNAP-01	04260498562060
LV6-C-U-W-07	04260498566754	C-NBP-USB	04260498565931	C-ADAPT-BANANA-SNAP-08	04260498568185
LV6-S-U-W-07	04260498566761	C-PC-BPM2	04260498564354	C-ADAPT-BANANA-TAB-01	04260498562077
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LF-C-E-W-07	04260498566495	-----	-----	ADAPT-M422-D-00-02	04260498567683
LF-S-E-W-07	04260498566501	C-1200M-RS232	04260498562329	ADAPT-M422-K-00-02	04260498567690
LL-C-E-W-07	04260498566518	C-1200M-USB	04260498564330	ADAPT-Q422-D-00-02	04260498567959
LL-S-E-W-07	04260498566525	C-1200S-RS232	04260498562336	ADAPT-Q422-K-00-02	04260498567966
LN-C-E-W-07	04260498566570	C-1200S-USB	04260498561896	Q422-D-00-01	04260498564323
LN-S-E-W-07	04260498566587	C-USB-1200HR	04260498562374	-----	-----
LR-C-E-W-07	04260498566594	C-USB-NHH	04260498562442	C-BELT-ECG-DSP-01	04260498562459
LR-S-E-W-07	04260498566600	-----	-----	C-BELT-ECG-UH-01	04260498562466
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LLA-C-U-W-07	04260498566532	C-USBA-1.5M-EI-07	04260498567881	NR-314P-BELT-01	04260498568147
LLA-S-U-W-07	04260498566549	C-USB-AB (mini)1.5	04260498564316	NR-314P-BELT-02	04260498568154