

BSI Migration of Certificates from UK Notified Body (0086) to NL Notified Body (2797)

BSI operates two full scope Notified Bodies, which cover all NBOG codes for the Medical Device Directives (MDD, AIMD, and IVDD):

United Kingdom	Netherlands
Notified Body Number 0086	Notified body number 2797
BSI Kitemark Court Davy Avenue Milton Keynes MK5 8PP	BSI Group The Netherlands B.V. Say Building John M. Keynesplein 9 1066 EP Amsterdam

Please Note: This letter provides validation only where BSI NB 2797 certificate(s) accompany the document.

The named manufacturer has completed migration of the enclosed CE certificate(s), originally issued by BSI UK (0086) Notified Body to BSI Group The Netherlands B.V. which is a European Notified Body designated in The Netherlands for the following three directives: MDD (93/42/EEC), AIMDD (90/385/EEC) and IVDD (98/79/EC).

The migrated certificates retain their original certificate references to ensure traceability and to maintain full visibility of the significant history of the previous certification changes for the product or product family concerned. BSI Group The Netherlands B.V will maintain and continue with the full surveillance audit schedule set previously by BSI UK. The maintained traceability ensures all regulatory requirements under the Directives remain valid and assessed on an ongoing basis and manufacturers do not need to update their labelling immediately.

Your Sincerely



Gary Slack

SVP Notified Body and Brexit Strategist,

EC Certificate - Product Quality Assurance

Directive 93/42/EEC on Medical Devices, Annex VI

No. **CE 663101**
Issued To: **NORAV Medical GmbH**
Christof-Ruthof-Weg 10
Mainz-Kastel
55252
Germany

In respect of:

Final testing of products for cardio-pulmonary diagnostics.**Endkontrolle von Produkten für die kordio-pulmologische Diagnostik.**

on the basis of our examination of the quality assurance system under the requirements of Council Directive 93/42/EEC, Annex VI. The quality assurance system meets the requirements of the directive. For the placing on the market of class IIb products, an Annex III certificate is required.

For and on behalf of BSI, a Notified Body for the above Directive (Notified Body Number 2797):



Gary E Slack, Senior Vice President Medical Devices

First Issued: **2018-01-29**Date: **2020-07-24**Expiry Date: **2023-01-28**

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Page 1 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Product Quality Assurance

Supplementary Information to CE 663101

Issued To:

**NORAV Medical GmbH
Christof-Ruthof-Weg 10
Mainz-Kastel
55252
Germany**

NBOG code(s)	Device Description	Intended purpose per IFU
Class IIa		
MD 1301 MDS 7010	Norav PC-ECG 1200 Series for Resting-ECG and Stress-Test-ECG.	N/A for class IIa
MD 1111	Software options for Norav PC-ECG 1200 Series.	N/A for class IIa
MD 1301 MDS 7010	Wireless recording of ECG Signals in Rehabilitation Measure.	N/A for class IIa
MD 1111	Software to control the recording of ECG Signals in Rehabilitation Measures	N/A for class IIa
MD 1111	Analysis Software to analyze Ambulatory ECG Recordings made with Holter Recorder	N/A for class IIa
MD 1301 MDS 7010	Ambulatory Recording of 3- or 12 Channels of ECG for up to 14 day	N/A for class IIa

First Issued: **2018-01-29**

Date: **2020-07-24**

Expiry Date: **2023-01-28**

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Page 2 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

EC Certificate - Product Quality Assurance

Supplementary Information to CE 663101

Issued To:

**NORAV Medical GmbH
Christof-Ruthof-Weg 10
Mainz-Kastel
55252
Germany**

NBOG code(s)	Device Description	Intended purpose per IFU
Class IIa		
MD 1301 MDS 7010	Electro-Cardiographs (with integrated Thermal Printer) to Record ECG Signals for Resting-ECG	N/A for class IIa
MD 1301 MDS 7010	PC Based Spirometer	N/A for class IIa
MD 1111	Software to control of the PC based Spirometer and to Analyze the Measured Values	N/A for class IIa

First Issued: **2018-01-29**

Date: **2020-07-24**

Expiry Date: **2023-01-28**

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Page 3 of 3

Validity of this certificate is conditional on the quality system being maintained to the requirements of the Directive as demonstrated through the required surveillance activities of the Notified Body. This approval excludes all products designed and/or manufactured by a third party on behalf of the company named on this certificate, unless specifically agreed with BSI.
This certificate was issued electronically and is bound by the conditions of the contract.

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016 & EN ISO 13485:2016

This is to certify that:

NORAV Medical GmbH
Christof-Ruthof-Weg 10
Mainz-Kastel
55252
Germany

Holds Certificate Number:

MD 663099

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 & EN ISO 13485:2016 for the following scope:

Manufacture, distribution, and servicing of products for cardio-pulmonary diagnostics.
Herstellung, Vertrieb und Wartung von Produkten für die kardio-pulmologische Diagnostik.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2017-01-23

Latest Revision Date: 2021-05-05

Effective Date: 2021-05-07


Expiry Date: 2024-05-06

Page: 1 of 1



003

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Document Title:	EC DECLARATION OF CONFORMITY			
Document No:	NV_01-00-05	Revision: 07	Date: 25.01.2021	Page: 1 of 5

We, the

Norav Medical GmbH

Christof-Ruthof-Weg 10
55252 Mainz-Kastel
Germany

hereby declare under our sole responsibility that the Medical Device(s) specified on the next pages conform to and meet the full provisions of the *Medical Devices Directive 93/42 EEC* as amended by the *Directive 2007/47/EC*.

All Medical Device(s) specified have been classified in accordance with the Medical Devices Directive classification rules of **Annex IX, Rule 10**, which is: *“Active devices intended for diagnoses are in Class IIa...”*

Therefore, the Applicable Classification is: **Class IIa**

The control of product quality and the conformity with the above-mentioned *Medical Devices Directive 93/42/EEC* is continuously assessed utilizing *Incoming Inspection and Final Inspection* of each individual Device in accordance with the requirements of **Annex VI** coupled with **Annex VII, sections 1 to 4 and 6** of the MDD (*Quality Assurance Product*).

The processes of the *Incoming Inspection and Final Inspection* are supported by the *Quality Management System* which has been implemented and is maintained by Norav Medical GmbH in accordance with the ISO 13485:2016. For the approval of the conformity of the *Quality Management System* with the requirements of Annex VI of the Directive we have appointed the Certification Body:

BSI - British Standard Institution

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

Notified Body ID:	2797	(former 0086)	
ISO Certificate no.:	MD 663099	Issue date: 07.05.2021	Expiry date: 06.05.2024
EC Certificate no.:	CE 663101	Issue date: 24.07.2020	Expiry date: 28.01.2023

This EC Declaration of Conformity is valid from its issuance until the expiry date of the accompanying CE Certificate (see above). Any alteration to one of the Medical Device(s) covered by this declaration will immediately invalidate this declaration.

Authorised Signatory:

Willi Schlosser
Name

07.05.2021, **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

List of the Standards applied:

The Medical Device(s) specified on the next page have been designed and manufactured in accordance with the standards listed hereunder. The Norav Medical GmbH will update once every year and ensures to keep the last revision of each standard.

Standard	Description
MDD 93/42/EEC	<i>Medical Devices Directive of the European Council, as amended by the directive 2007/47/EC</i>
EN ISO 13485:2016	<i>Medical Devices – Quality Management Systems – Requirements for regulatory purposes</i>
EN ISO 15223-1:2016	<i>Symbols to be used with medical device labels, labelling and information to be supplied -- Part 1: General requirements</i>
EN 1041:2008	<i>Information supplied by the manufacturer of medical devices</i>
CFR part 820	<i>FDA CFR – Code Of Federal Requirements</i>
SOR/98-282	<i>Canada – Medical Devices Regulations</i>
1999/5/EC (R&TTE)	<i>Directive of the European Council on Radio & Telecommunications Terminal Equipment (Radio Equipment Directive RED)</i>
2002/96/EC	<i>Directive of the European Council on the Waste Electrical and Electronic Equipment (WEEE)</i>
IEC60601-1(2005) & AM1 (2012)	<i>General safety requirements for basic safety and essential performance</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>
2014/30/EU	<i>Directive of the European Council on the Electromagnetic Compatibility</i>
2014/53/EU	<i>Directive of the European Council on Radio Equipment (R&TTE)</i>
IEC 62304:2006	<i>International Standard for Medical Devices Software Lifecycle Processes</i>
IEC 62366-1:2015	<i>Medical devices -- Part 1: Application of usability engineering to medical devices</i>
ISO 14971:2012	<i>Medical Devices – Application of Risk Management to Medical Devices</i>
IEC60601-1-6:2010 & AM (2013)	<i>General requirements for basic safety and essential performance Collateral standard: Usability</i>
IEC60601-1-11-2015 (2 nd Edition)	<i>General requirements for basic safety and essential performance Collateral standard: Requirements for Medical Electrical Equipment and Medical Electrical Systems used in the Home Healthcare Environment</i>
IEC 60601-2-25 (2011)	<i>Medical Electrical Equipment: Particular requirements for the basic safety and essential performance of Electro-Cardiographs</i>
EN60601-1-2 (2007)	<i>General requirements for basic safety and essential performance Collateral standard: Electro-Magnetic Compatibility (EMC) – Requirements and Tests</i>
EN60601-2-47 -2012 (2 nd Edition)	<i>Medical electrical equipment: Particular requirements for the basic safety and essential performance of Ambulatory Electro-Cardiographic Systems, second edition</i>

Products covered by this declaration:

Product	Catalogue No.	UDI-DI No.	Description
PC-ECG 1200HR	1200HR-K-00-E-B10-05	04260498567515	High Res. ECG, Rest & Stress, LO, Kit, NV, Ban., IEC type, 10L cable, DE
PC-ECG 1200HR	1200HR-K-00-E-C10-04	04260498567522	High Res. ECG, Rest & Stress, LO, Kit, NV, Clip, IEC type, 10L cable, DE
PC-ECG 1200HR	1200HR-K-00-E-S10-04	04260498566877	High Res. ECG, Rest & Stress, LO, Kit, NV, Snap, IEC type, 10L cable, DE
PC-ECG 1200HR	1200HR-K-00-U-B10-05	04260498567539	High Res. ECG, Rest & Stress, LO, Kit, NV, Ban., AHA type, 10L cable, DE
PC-ECG 1200HR	1200HR-K-00-U-C10-03	07290110255398	High Res. ECG, Rest & Stress, LO, Kit, NV, Clip, AHA type, 10L cable, IL
PC-ECG 1200HR	1200HR-K-00-U-C10-04	04260498567546	High Res. ECG, Rest & Stress, LO, Kit, NV, Clip, AHA type, 10L cable, DE
PC-ECG 1200HR	1200HR-K-00-U-S10-04	04260498567553	High Res. ECG, Rest & Stress, LO, Kit, NV, Snap, AHA type, 10L cable, DE
PC-ECG 1200M	1200M-K-00-E-B10-04	04260498564477	PCECG, Rest, Kit, NV, Ban., IEC type, 10L cable, ECG SW + Option I3, DE
PC-ECG 1200M	1200M-K-00-E-B10-05	04260498561872	PCECG, Rest, Kit, NV, Ban., IEC type, 10L cable, USB cable, ECG-SW, DE
PC-ECG 1200M	1200M-K-00-E-C10-05	04260498564484	PCECG, Rest, Kit, NV, Clip, IEC type, 10L cable, DE
PC-ECG 1200M	1200M-K-00-E-S10-04	04260498564507	PCECG, Rest, Kit, NV, Snap, IEC type, 10L cable, ECG SW + Option I3, DE
PC-ECG 1200M	1200M-K-00-E-S10-05	04260498564491	PCECG, Rest, Kit, NV, Snap, IEC type, 10L cable, DE
PC-ECG 1200M	1200M-K-00-U-B10-04	04260498564514	PCECG, Rest, Kit, NV, Ban., AHA type, 10L cable, ECG SW + Optn. I3, DE
PC-ECG 1200M	1200M-K-00-U-B10-05	04260498564521	PCECG, Rest, Kit, NV, Ban., AHA type, 10L cable, USB cable, ECG-SW, DE
PC-ECG 1200M	1200M-K-00-U-C10-05	04260498564538	PCECG, Rest, Kit, NV, Clip, AHA type, 10L cable, DE
PC-ECG 1200M	1200M-K-00-U-S10-04	04260498564552	PCECG, Rest, Kit, NV, Snap, AHA type, 10L cable, ECG SW + Optn. I3, DE
PC-ECG 1200M	1200M-K-00-U-S10-05	04260498564545	PCECG, Rest, Kit, NV, Snap, AHA type, 10L cable, DE
PC-ECG 1200S	1200S-K-00-E-B10-05	04260498564576	PCECG, Rest & Stress, Kit, NV, Banana, IEC type, 10L cable, DE
PC-ECG 1200S	1200S-K-00-E-C10-03	04260498564583	PCECG, Rest & Stress, Kit, NV, Clip, IEC type, 10L cable, SW-S2I3D1, DE
PC-ECG 1200S	1200S-K-00-E-C10-05	04260498564590	PCECG, Rest & Stress, Kit, NV, Clip, IEC type, 10L cable, DE
PC-ECG 1200S	1200S-K-00-E-S10-03	04260498564569	PCECG, Rest & Stress, Kit, NV, Snap, IEC type, 10L cable, DE
PC-ECG 1200S	1200S-K-00-E-S10-05	04260498561889	PCECG, Rest & Stress, Kit, NV, Snap, IEC type, 10L cable, DE
PC-ECG 1200S	1200S-K-00-U-C10-03	04260498564606	PCECG, Rest & Stress, Kit, NV, Clip, AHA type, 10L cable, SW-S2I3D1, DE
PC-ECG 1200S	1200S-K-00-U-C10-05	04260498564613	PCECG, Rest & Stress, Kit, NV, Clip, AHA type, 10L cable, DE
PC-ECG 1200S	1200S-K-00-U-S10-03	04260498564620	PCECG, Rest & Stress, Kit, NV, Snap, AHA type, 10L cable, DE
PC-ECG 1200S	1200S-K-00-U-S10-05	04260498564637	PCECG, Rest & Stress, Kit, NV, Snap, AHA type, 10L cable, DE
PC-ECG 1200T3	1200T3-K-00-U-C3-05	04260498567560	PCECG, Rest & Stress, Kit, NV, 5V Trigger out selectable CH, Kit, NV, Clip, AHA type, 3L cable, DE
PC-ECG 1200W2	1200W2-K-00-E-C10-09	04260498564644	Wireless ECG, Rest & Stress, Kit, NV, Clip, IEC type, 10L cable, DE
PC-ECG 1200W2	1200W2-K-00-E-C10-10	04260498564651	Wireless ECG, Rest & Stress, Kit, NV, Clip, IEC type, 10L, SW-S1, DE
PC-ECG 1200W2	1200W2-K-00-E-C10-11	04260498564668	Wireless ECG, Rest & Stress, Kit, NV, Clip, IEC type, 10L, SW-S2, DE
PC-ECG 1200W2	1200W2-K-00-E-C10-12	04260498564675	Wireless ECG, Rest & Stress, Kit, NV, Clip, IEC type, 10L, SW-S2I2D1, DE
PC-ECG 1200W2	1200W2-K-00-E-C10-13	04260498564682	Wireless ECG, Rest & Stress, Kit, NV, Clip, IEC type, 10L, SW-S2I3D1, DE
PC-ECG 1200W2	1200W2-K-00-E-C10-14	04260498564699	Wireless ECG, Rest & Stress, Kit, NV, Clip, IEC type, 10L, SW-S2D1, DE
PC-ECG 1200W2	1200W2-K-00-E-C10-15	04260498564705	Wireless ECG, Rest & Stress, Kit, NV, Clip, IEC type, 10L, SW-RFID2, DE
PC-ECG 1200W2	1200W2-K-00-E-C10-16	04260498564712	Wireless ECG, Rest & Stress, Kit, NV, Clip, IEC type, 10L, SW-RFID3, DE
PC-ECG 1200W2	1200W2-K-00-E-C10-19	04260498567423	Wireless ECG, Rest & Stress, Kit, NV, Clip, IEC type, 10L, WRV2, DE
PC-ECG 1200W2	1200W2-K-00-E-S10-09	04260498561933	Wireless ECG, Rest & Stress, Kit, NV, Snap, IEC type, 10L cable, DE
PC-ECG 1200W2	1200W2-K-00-E-S10-10	04260498564729	Wireless ECG, Rest & Stress, Kit, NV, Snap, IEC type, 10L, SW-S1, DE
PC-ECG 1200W2	1200W2-K-00-E-S10-11	04260498564736	Wireless ECG, Rest & Stress, Kit, NV, Snap, IEC type, 10L, SW-S2, DE
PC-ECG 1200W2	1200W2-K-00-E-S10-12	04260498564743	Wireless ECG, Rest & Stress, Kit, NV, Snap, IEC typ., 10L, SW-S2I2D1, DE
PC-ECG 1200W2	1200W2-K-00-E-S10-13	04260498564750	Wireless ECG, Rest & Stress, Kit, NV, Snap, IEC typ., 10L, SW-S2I3D1, DE
PC-ECG 1200W2	1200W2-K-00-E-S10-14	04260498564767	Wireless ECG, Rest & Stress, Kit, NV, Snap, IEC type, 10L, SW-S2D1, DE
PC-ECG 1200W2	1200W2-K-00-E-S10-15	04260498564774	Wireless ECG, Rest & Stress, Kit, NV, Snap, IEC type, 10L, SW-RFID2, DE
PC-ECG 1200W2	1200W2-K-00-E-S10-16	04260498564781	Wireless ECG, Rest & Stress, Kit, NV, Snap, IEC type, 10L, SW-RFID3, DE

Product	Catalogue No.	UDI-DI No.	Description
PC-ECG 1200W2	1200W2-K-00-E-S10-18	04260498564170	ECG, Rest & Stress, Kit, NV, Snap, IEC type, 10L Belt, DE
PC-ECG 1200W2	1200W2-K-00-E-S10-20	04260498567461	Wireless ECG, Rest & Stress, Kit, NV, Snap, IEC type, 10L, WRV2, DE
PC-ECG 1200W2	1200W2-K-00-U-C10-09	04260498564798	Wireless ECG, Rest & Stress, Kit, NV, Clip, AHA type, 10L cable, DE
PC-ECG 1200W2	1200W2-K-00-U-C10-10	04260498564804	Wireless ECG, Rest & Stress, Kit, NV, Clip, AHA type, 10L, SW-S1, DE
PC-ECG 1200W2	1200W2-K-00-U-C10-11	04260498564811	Wireless ECG, Rest & Stress, Kit, NV, Clip, AHA type, 10L, SW-S2, DE
PC-ECG 1200W2	1200W2-K-00-U-C10-12	04260498564828	Wireless ECG, Rest & Stress, Kit, NV, Clip, AHA typ., 10L, SW-S2I2D1, DE
PC-ECG 1200W2	1200W2-K-00-U-C10-13	04260498564835	Wireless ECG, Rest & Stress, Kit, NV, Clip, AHA typ., 10L, SW-S2I3D1, DE
PC-ECG 1200W2	1200W2-K-00-U-C10-14	04260498564842	Wireless ECG, Rest & Stress, Kit, NV, Clip, AHA type, 10L, SW-S2D1, DE
PC-ECG 1200W2	1200W2-K-00-U-C10-15	04260498564859	Wireless ECG, Rest & Stress, Kit, NV, Clip, AHA type, 10L, SW-RFID2, DE
PC-ECG 1200W2	1200W2-K-00-U-C10-16	04260498564866	Wireless ECG, Rest & Stress, Kit, NV, Clip, AHA type, 10L, SW-RFID3, DE
PC-ECG 1200W2	1200W2-K-00-U-C10-19	04260498567485	Wireless ECG, Rest & Stress, Kit, NV, Clip, AHA type, 10L, WRV2, DE
PC-ECG 1200W2	1200W2-K-00-U-C10-21	04260498567577	Wireless ECG, Rest & Stress, Kit, NV, Clip, AHA type, 10L, WRV2, DE
PC-ECG 1200W2	1200W2-K-00-U-S10-09	04260498564873	Wireless ECG, Rest & Stress, Kit, NV, Snap, AHA type, 10L cable, DE
PC-ECG 1200W2	1200W2-K-00-U-S10-10	04260498564880	Wireless ECG, Rest & Stress, Kit, NV, Snap, AHA type, 10L, SW-S1, DE
PC-ECG 1200W2	1200W2-K-00-U-S10-11	04260498564897	Wireless ECG, Rest & Stress, Kit, NV, Snap, AHA type, 10L, SW-S2, DE
PC-ECG 1200W2	1200W2-K-00-U-S10-12	04260498564903	Wireless ECG, Rest & Stress, Kit, NV, Snap, AHA tp., 10L, SW-S2I2D1, DE
PC-ECG 1200W2	1200W2-K-00-U-S10-13	04260498564910	Wireless ECG, Rest & Stress, Kit, NV, Snap, AHA tp., 10L, SW-S2I3D1, DE
PC-ECG 1200W2	1200W2-K-00-U-S10-14	04260498564927	Wireless ECG, Rest & Stress, Kit, NV, Snap, AHA type, 10L, SW-S2D1, DE
PC-ECG 1200W2	1200W2-K-00-U-S10-15	04260498564934	Wireless ECG, Rest & Stress, Kit, NV, Snap, AHA typ., 10L, SW-RFID2, DE
PC-ECG 1200W2	1200W2-K-00-U-S10-16	04260498564941	Wireless ECG, Rest & Stress, Kit, NV, Snap, AHA typ., 10L, SW-RFID3, DE
PC-ECG 1200W2	1200W2-K-00-U-S10-18	04260498564163	ECG, Rest & Stress, Kit, NV, Snap, AHA type, 10L Belt, DE
PC-ECG 1200W2	1200W2-K-00-U-S10-22	04260498567508	Wireless ECG, Rest & Stress, Kit, NV, Snap, AHA type, 10L, WRV2, DE
PC-ECG 1200W2	1200W2-K-01-E-S10-02	04260498564958	Wireless ECG, Rest & Stress, W2, Kit, COSMED, Snap, IEC type, 10L, DE
PC-ECG 1200W2	1200W2-K-01-U-S10-02	04260498564965	Wireless ECG, Rest & Stress, W2, Kit, COSMED, Snap, AHA type, 10L, DE
PC-ECG 1200W2	1200W2-K-04-E-C10-03	04260498566914	Wireless ECG, Rest & Stress, Kit, GE, Clip, IEC type, 10L cable, DE
PC-ECG 1200W2	1200W2-K-04-E-C10-04	04260498566938	Wireless ECG, Rest & Stress, Kit, Service, GE, Clip, IEC type, 10L, DE
PC-ECG 1200W2	1200W2-K-04-U-C10-03	04260498566921	Wireless ECG, Rest & Stress, Kit, GE, Clip, AHA type, 10L cable, DE
PC-ECG 1200W2	1200W2-K-04-U-C10-04	04260498566952	Wireless ECG, Rest & Stress, Kit, Service, GE, Clip, AHA type, 10L, DE
ECGUSB1DEX	ECGUSB1DEX-K-00-04	04260498564279	ECG Module Add On, 1CH, Kit, NV, Samsung m., DE
ECGUSB1DEX	ECGUSB1DEX-K-00-06	04260498565856	ECG Module Add On, 1CH, Kit, NV, FW11, GE Wuxi, DE
ECGUSB1DEX	ECGUSB1DEX-K-00-EC3-05	04260498564255	ECG Module Add On, 1CH, Kit, NV, FW11, Clip, IEC type, 3L, GEIL, DE
ECGUSB1DEX	ECGUSB1DEX-K-00-EC3-06	04260498567584	ECG Module Add On, 1CH, Kit, NV, Clip, IEC type, 3L cable, DE
ECGUSB1DEX	ECGUSB1DEX-K-00-EC3-08	04260498566099	ECG Module Add On, 1CH, Kit, NV, FW11, Clip, IEC typ., 3L, GEIL, DOK
ECGUSB1DEX	ECGUSB1DEX-K-00-EC3-11	04260498566884	ECG Module Add On, 1CH, Kit R2, NV, FW11, Clip, IEC typ., 3L, GEIL, DE
ECGUSB1DEX	ECGUSB1DEX-K-00-EC3-12	04260498567003	ECG Module Add On, 1CH, Kit R2, NV, FW11, Clip, IEC typ., 3L, GE, DE
ECGUSB1DEX	ECGUSB1DEX-K-00-EC3-14	04260498567027	ECG Module Add On, 1CH, Kit R2, NV, FW11, Clip, IEC typ., 3L, GEAU
ECGUSB1DEX	ECGUSB1DEX-K-00-UC3-05	04260498564248	ECG Module Add On, 1CH, Kit, NV, FW11, Clip, AHA type, 3L, GEIL, DE
ECGUSB1DEX	ECGUSB1DEX-K-00-UC3-06	04260498567591	ECG Module Add On, 1CH, Kit, NV, Clip, AHA type, 3L cable, DE
NR1207	NR1207-K-00-E-S10-04	04260498565375	ECG Holter, NR2, 12CH/7days, Kit, NV, Snap, IEC type, 10L, DE
NR1207	NR1207-K-00-U-S10-04	04260498565399	ECG Holter, NR2, 12CH/7days, Kit, NV, Snap, AHA type, 10L, DE
NR1207-3	NR12073-K-00-EB10S5-04	04260498565436	Wireless ECG, NR2, 3In1, Kit, NV, IEC type, Banana 10L, Snap 5L, i, DE
NR1207-3	NR12073-K-00-UB10S5-04	04260498565450	Wireless ECG, NR2, 3In1, Kit, NV, AHA type, Banana 10L, Snap 5L, i, DE
NR1207-E	NR1207E-K-00-E-B10-04	04260498565498	Wireless ECG, NR2, Rest & Stress, Kit, NV, Banana, IEC type, 10L, i, DE
NR1207-E	NR1207E-K-00-E-C4-04	04260498565511	Wireless ECG, NR2, Rest & Stress, Kit, NV, Clip, IEC type, 4L cable, i, DE
NR1207-E	NR1207E-K-00-U-B10-04	04260498565542	Wireless ECG, NR2, Rest & Stress, Kit, NV, Banana, AHA type, 10L, i, DE
NR1207-E	NR1207E-K-00-U-C4-04	04260498565566	Wireless ECG, NR2, Rest & Stress, Kit, NV, Clip, AHA type, 4L cable, i, DE

Product	Catalogue No.	UDI-DI No.	Description
NR302	NR302-K-00-E-S7-04	04260498565115	ECG Holter, NR2, 3CH/48h, Kit, NV, Snap, IEC type, 7L cable, DE
NR302	NR302-K-00-U-S3-04	04260498565139	ECG Holter, NR2, 3CH/48h, Kit, NV, Snap, AHA type, 3L cable, DE
NR302	NR302-K-00-U-S5-04	04260498565092	ECG Holter, NR2, 3CH/48h, Kit, NV, Snap, AHA type, 3L cable, DE
NR302	NR302-K-00-U-S7-04	04260498565153	ECG Holter, NR2, 3CH/48h, Kit, NV, Snap, AHA type, 7L cable, DE
NR314	NR314-K-00-E-S7-04	04260498565214	ECG Holter, NR2, 3CH/14days, Kit, NV, Snap, IEC type, 7L cable, DE
NR314	NR314-K-00-U-S3-04	04260498565238	ECG Holter, NR2, 3CH/14days, Kit, NV, Snap, AHA type, 3L cable, DE
NR314	NR314-K-00-U-S5-04	04260498565191	ECG Holter, NR2, 3CH/14days, Kit, NV, Snap, AHA type, 5L cable, DE
NR314	NR314-K-00-U-S7-04	04260498565252	ECG Holter, NR2, 3CH/14days, Kit, NV, Snap, AHA type, 7L cable, DE
NR314-T	NR314T-K-00-E-C4-03	04260498565306	ECG Telemetry, NR, Transmitter, Kit, NV, Clip, IEC type, 4L cable, DE
NR314-T	NR314T-K-00-E-C4-04	04260498565313	ECG Telemetry, NR2, Transmitter, Kit, NV, Clip, IEC type, 4L cable, DE
NR314-T	NR314T-K-00-U-C4-03	04260498565337	ECG Telemetry, NR, Transmitter, Kit, NV, Clip, AHA type, 4L cable, DE
NR314-T	NR314T-K-00-U-C4-04	04260498565320	ECG Telemetry, NR2, Transmitter, Kit, NV, Clip, AHA type, 4L cable, DE
NR314-T	NR314T-K-00-U-S5-04	04260498566860	ECG Telemetry, NR2, Transmitter, Kit, NV, Snap, AHA type, 5L, DE
NECG-3	NECG3-K-00-E-B10-01	04260498560837	Conventional 3CH ECG, int. Thermal Prnt., Banana, IEC type, 10L, DE
NECG-3	NECG3-K-00-U-B10-01	04260498560875	Conventional 3CH ECG, int. Thermal Prnt., Banana, AHA type, 10L, DE
NECG-12	NECG12-K-00-E-B10-01	04260498560561	Conventional 12CH ECG, int. Thermal Prnt., Banana, IEC type, 10L, DE
NECG-12	NECG12-K-00-U-B10-01	04260498565580	Conventional 12CH ECG, int. Thermal Prnt., Banana, AHA type, 10L, DE
NECG-12C	NECG12C-K-00-E-B10-01	04260498560592	Conv. 12CH ECG, Col.Dsp., int. Therm. Prnt., Banana, IEC type, 10L, DE
NECG-12C	NECG12C-K-00-U-B10-01	04260498566778	Conv. 12CH ECG, Col.Dsp., int. Therm. Prnt., Banana, AHA type, 10L, DE
NSpiro	NSPIRO	04260498561063	PC based easy to use USB-Spirometer Kit
NAmbi	NSPIRO-AMBI-STICK-01	04260498561070	Ambient Measuring Device for NSpiro
SW-NH-301	HASP-SW-K-NH301-Net-1	04260498562978	Stand Alone Analysis Software for Ambulatory ECG (Holter)
SW-NEMS-A	HASP-SW-K-NEMS-A-01	04260498562664	PC based data management tool for Local applications
SW-NEMS-Q	HASP-SW-K-NEMS-Q-01	04260498562671	PC based data management tool for Network applications
PC-ECG Option S1	HASP-SW-K-S1-01	04260498563012	Stress Test ECG Option
PC-ECG Option S2	HASP-SW-K-S2-01	04260498563029	Advanced Stress Test ECG Option
PC-ECG Option I1	HASP-SW-K-I1-01	04260498562824	Measurement tool for Resting ECG
PC-ECG Option I3	HASP-SW-K-I3-01	04260498562855	Measurement tool, incl. Automatic Interpretation
PC-ECG Option M1	HASP-SW-K-M1-01	04260498562879	12 lead long-term Resting ECG Option
PC-ECG Option L1	HASP-SW-K-L1-01	04260498562862	Late Potential Analysis Option
PC-ECG Option H1	HASP-SW-K-H1-01	04260498562817	Heart Rate Variability Analysis Option

We, the

Norav Medical GmbH

Christof-Ruthof-Weg 10
55252 Mainz-Kastel
Germany

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 *EU Medical Devices Regulation (2017/745)*. 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**. 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** *Medical devices – Quality Management Systems – Requirements for regulatory purposes.*
- EN ISO 15223-1:2016** *Medical devices – Symbols to be used with MD labels, labelling and information to be supplied.*
- EN ISO 14971:2012** *Medical devices – Application of risk management to medical devices.*
- EN 1041:2008+A1:2013** *Information supplied by the manufacturer of medical devices.*
- ANSI/AAMI EC53:2013** *ECG Trunk Cables and Patient Leadwires.*

The Applicable Codes and Terms are:

Global Location No.:	4260498560004	GMDN:	35748	<i>Cable / Lead</i>
Basic UDI-DI No.:	426049856DE55252NMCBLTD	UMDNS:	15754	<i>Cables / Leads, ECG</i>
EUDAMED – SRN	DE-MF-000006715			

Authorised Signatory:

Willi Schlosser
Name

08.06.2021, Mainz-Kastel
Date (dd.mm.yyyy) Place

Quality Affairs Manager
Position

Signature


Catalogue No.	UDI-DI No.	Catalogue No.	UDI-DI No.	Catalogue No.	UDI-DI No.
C3-C-E-ODU	04260498564293	C10-C-E-D-02	04260498561766	LL-C-E-W-07	04260498566518
C3-C-E-ODU-07	04260498566211	C10-C-E-D-03	04260498563883	LL-S-E-W-07	04260498566525
C3-C-E-ODU-08	04260498566372	C10-C-E-D-04	04260498560523	LLL-C-U-W-07	04260498566556
C3-C-E-ODU-1K	04260498565962	C10-C-E-D-10K-03	04260498564057	LLL-S-U-W-07	04260498566563
C3-C-LL-ODU-V	04260498566105	C10-C-E-EI-07	04260498566341	LN-C-E-W-07	04260498566570
C3-C-U-LL-D	04260498563074	C10-C-E-ODU	04260498562282	LN-S-E-W-07	04260498566587
C3-C-U-LL-D4R	04260498566112	C10-C-U-D-02	04260498562299	LR-C-E-W-07	04260498566594
C3-C-U-LL-D-FU	04260498566792	C10-C-U-D-04	04260498560530	LR-S-E-W-07	04260498566600
C3-C-U-LL-I-D	04260498566167	C10-C-U-D-10K-03	04260498564064	LRA-C-U-W-07	04260498566617
C3-C-U-LL-LA-D4R	04260498566075	C10-C-U-EI-07	04260498566358	LRA-S-U-W-07	04260498566624
C3-C-U-LL-ODUR	04260498565948	C10-C-U-ODU	04260498562305	LRL-C-U-W-07	04260498566631
C3-C-U-LL-ODUR-FU	04260498566136	C10-D-C-U-D	04260498561735	LRL-S-U-W-07	04260498566648
C3-C-U-LL-ODUR-W	04260498565993	C10-S-E-D-02	04260498561773	-----	-----
C3-C-U-ODU	04260498564309	C10-S-E-D-03	04260498562312	LV1-C-U-W-07	04260498566655
C3-C-U-ODU-07	04260498566228	C10-S-E-D-04	04260498560547	LV1-S-U-W-07	04260498566662
C3-C-U-ODU-08	04260498566389	C10-S-E-D-10K-03	04260498564019	LV2-C-U-W-07	04260498566679
C3-C-U-ODU-1K	04260498565979	C10-S-E-EI	04260498563968	LV2-S-U-W-07	04260498566686
C3-C-U-ODU-DA	04260498566013	C10-S-E-EI-07	04260498566266	LV3-C-U-W-07	04260498566693
C3D-C-U-ODU	04260498566020	C10-S-U-D-02	04260498561780	LV3-S-U-W-07	04260498566709
C3-ODU-EX	04260498565955	C10-S-U-D-04	04260498560554	LV4-C-U-W-07	04260498566716
C3-ODU-EX-FU	04260498565863	C10-S-U-D-10K-03	04260498564026	LV4-S-U-W-07	04260498566723
C3-ODU-EX-V	04260498566006	C10-S-U-EI	04260498563951	LV5-C-U-W-07	04260498566730
C3-S-U-EI	04260498563876	C10-S-U-EI-07	04260498566273	LV5-S-U-W-07	04260498566747
C3-S-U-EI-07	04260498566204	-----	-----	LV6-C-U-W-07	04260498566754
-----	-----	L10-B-E-W	04260498562572	LV6-S-U-W-07	04260498566761
C4-C-E-EI	04260498564002	L10-C-E-W-02	04260498562589	-----	-----
C4-C-E-EI-07	04260498566198	L10-C-E-W-07	04260498566303	C-ADAPT-BANANA-SNAP-01	04260498562060
C4-C-E-ODU	04260498562343	L10-C-E-W-L-02	04260498564101	C-ADAPT-BANANA-TAB-01	04260498562077
C4-C-E-ODU	04260498562343	L10-C-E-W-L1-07	04260498566983	C-DL800-PC5-3	04260498565870
C4-C-U-EI	04260498563999	L10-C-U-W-02	04260498562602	C-DL800-PC7-3	04260498565887
C4-C-U-EI-07	04260498566181	L10-C-U-W-07	04260498566310	C-DL900-PC-5-3	04260498565894
C4-C-U-ODU	04260498562350	L10-C-U-W-L-02	04260498564118	C-DL900-PC7-3	04260498565900
C4-C-U-ODU	04260498562350	L10-C-U-W-L1-07	04260498566990	C-DL900-USB	04260498565917
C4-S-U-D4R	04260498566068	L10-S-E-W- L1-07	04260498566976	-----	-----
-----	-----	L10-S-E-W-02	04260498562619	C-NBP-232	04260498565924
C5-S-U-EI	04260498563890	L10-S-E-W-07	04260498566327	C-NBP-USB	04260498565931
C5-S-U-EI-07	04260498566235	L10-S-E-W-L-02	04260498563906	C-PC-BPM2	04260498564354
-----	-----	L10-S-U-W-02	04260498562626	-----	-----
C7-S-E-EI	04260498563920	L10-S-U-W-07	04260498566334	C-1200M-RS232	04260498562329
C7-S-E-EI-07	04260498566242	L10-S-U-W-L-02	04260498564071	C-1200M-USB	04260498564330
C7-S-U-EI	04260498563913	L10-S-U-W-L1-07	04260498566969	C-1200S-RS232	04260498562336
C7-S-U-EI-07	04260498566259	-----	-----	C-1200S-USB	04260498561896
-----	-----	L3D-C-U-ODU	04260498566037	C-USB-1200HR	04260498562374
C10-B-E-D-02	04260498561742	LC1-C-E-W-07	04260498566785	C-USB-1.5M-EI	04260498563937
C10-B-E-D-03	04260498562244	LC1-S-E-W-07	04260498566945	C-USB-1.5M-EI-07	04260498566365
C10-B-E-D-04	04260498560509	LC2-C-E-W-07	04260498566396	C-USB-AB (mini)1.5	04260498564361
C10-B-E-D-06	04260498566143	LC2-S-E-W-07	04260498566402	C-USB-AB (mini)1.5	04260498564316
C10-B-E-D-10K-03	04260498564040	LC3-C-E-W-07	04260498566419	C-USB-AB(MINI)3	04260498562398
C10-B-E-D-M	04260498562251	LC3-S-E-W-07	04260498566426	C-USB-AB0.5	04260498562381
C10-B-E-EI	04260498563982	LC4-C-E-W-07	04260498566433	C-USB-AB2	04260498562404
C10-B-E-EI-07	04260498566280	LC4-S-E-W-07	04260498566440	C-USB-AB3	04260498562411
C10-B-E-ODU	04260498563050	LC5-C-E-W-07	04260498566457	C-USB-AB5	04260498562428
C10-B-U-D-02	04260498561759	LC5-S-E-W-07	04260498566464	C-USB-EXT	04260498562435
C10-B-U-D-03	04260498562268	LC6-C-E-W-07	04260498566471	C-USB-EXT	04260498562435
C10-B-U-D-04	04260498560516	LC6-S-E-W-07	04260498566488	C-USB-NHH	04260498562442
C10-B-U-D-10K-03	04260498564033	-----	-----	-----	-----
C10-B-U-D-M	04260498562275	LF-C-E-W-07	04260498566495	C-BNC-3m	04260498562367
C10-B-U-EI	04260498563975	LF-S-E-W-07	04260498566501	-----	-----
C10-B-U-EI-07	04260498566297	LLA-C-U-W-07	04260498566532	C-RS422-MM-Q422	04260498564347
C10-B-U-ODU	04260498563067	LLA-S-U-W-07	04260498566549	Q422-D-00-01	04260498564323