EU Quality Management Certificate

This is to certify that the company

SOMNOmedics AG

Am Sonnenstuhl 63
97236 Randersacker
Germany

SRN: DE-MF-000006921

has established, implemented and maintains a Quality Management System in accordance with

Annex IX, Chapter I and III of the Regulation (EU) 2017/745

Conformity Assessment based on a Quality Management System and on Assessment of Technical Documentation

for the device categories and products listed in the Annex of this certificate.

The conformity of the Quality Management System has been verified in an audit and is subject to regular surveillance in accordance with Annex IX, Chapter 1, Section 3.
Limitations to this certificate are listed in the Annex.

Devices listed in the Annex may bear the CE marking with the identification number of the Notified Body (0297).

For placing of devices of class III and devices class IIb implantable according to Article 52(4) subparagraph 2 listed in the Annex on the market, an additional certificate according to Annex IX, Chapter II is required.

Certificate registration no.	390353 MDR2017Q
Certificate ID	1000120947
Effective date	2024-06-13
Expiry date	2029-06-12
Frankfurt am Main,	2024-06-13

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-094

DQS Medizinprodukte GmbH

Sigrid Uhlemann
Managing Director

Michael Bothe
Head of Certification Body
(active medical devices)

Szymon Kurdyn
Head of Certification Body
(non-active medical devices)

Accredited Body: DQS Medizinprodukte GmbH, August-Schanz-Str. 21, 60433 Frankfurt am Main
DQS Medizinprodukte GmbH is a Notified Body according to Regulation (EU) 2017/745 of the Council concerning medical devices with the Identification Number 0297.
The validity of this certificate can only be verified by the QR-code.

420.90 Version 6.0

Annex to EU Quality Management Certificate
SRN of Manufacturer: DE-MF-000006921
Certificate ID: 1000120947

Device categories and variants covered by this certificate:

Device category:	**MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**
Product name:	SOMNOwatch™ plus
Risk classification:	IIa
Basic-UDI-DI:	42504134SOWPLK
Intended purpose:	The SOMNOwatch™ plus is a portable, miniaturized multi-channel measuring system for recording physiological signals on an outpatient basis. The SOMNOwatch™ plus helps the doctor to diagnose sleep disorders.

Device category:	**MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**
Product name:	HomeSleepTest (REM+)
Risk classification:	IIa
Basic-UDI-DI:	42504134HSTRW
Intended purpose:	The HomeSleepTest (REM+) is a portable, miniaturized multi-channel measurement system for recording physiological signals in the home environment. The HomeSleepTest (REM+) helps doctors to diagnose sleep disorders.

Device category:	**MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**
Product name:	ABPMpro
Risk classification:	IIa
Basic-UDI-DI:	42504134ABPMDR
Intended purpose:	The ABPMpro is a portable device for recording physiological signals. The ABPMpro is used as a long-term blood pressure and long-term ECG device.

Device category:	**MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**
Product name:	SOMNOtouch™ NIBP
Risk classification:	IIa
Basic-UDI-DI:	42504134SOTNIBPQ2
Intended purpose:	The SOMNOtouch™ NIBP is a portable device for recording physiological signals. The SOMNOtouch™ NIBP is used as a long-term blood pressure and long-term ECG device.

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Device category:	**MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**
Product name:	SOMNOtouch™ RESP (eco)
Risk classification:	IIa
Basic-UDI-DI:	42504134PSGSC
Intended purpose:	The SOMNOtouch™ RESP (eco) is a portable device for recording physiological signals, which is used by the doctor as a polygraphy (PG) system to help diagnose sleep disorders.

Device category:	**MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**
Product name:	SOMNOtouch™ RESP PSG
Risk classification:	IIa
Basic-UDI-DI:	42504134PSGSC
Intended purpose:	The SOMNOtouch™ PSG is a portable device for recording physiological signals, which serves as a polysomonography (PSG) system to help doctors diagnose sleep disorders.

Device category:	**MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**
Product name:	Sleep Adagio® PG (pro)
Risk classification:	IIa
Basic-UDI-DI:	42504134SleepA36
Intended purpose:	The Sleep Adagio® PG (pro) is a portable device for recording physiological signals, which is used by the doctor as a polygraphy (PG) system to assist in the diagnosis of sleep disorders.

Device category:	**MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**
Product name:	Sleep Adagio® PSG (pro)
Risk classification:	IIa
Basic-UDI-DI:	42504134SleepA36
Intended purpose:	The Sleep Adagio® is a portable device for recording physiological signals, which is used by the doctor as a polygraphy (PG) or polysomnography (PSG) system to assist in the diagnosis of sleep disorders.

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Device category:	**MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**
Product name:	SOMNO HD (eco)
Risk classification:	IIa
Basic-UDI-DI:	42504134HD59
Intended purpose:	The SOMNO HD (eco) is a portable device for the continuous recording of physiological signals. It can be used by the doctor both as a polysomnography (PSG) system to assist in the diagnosis of sleep disorders and as a long-term EEG device.

Device category:	**MDA 0203 - Active non-implantable devices for monitoring of vital physiological parameters**
Product name:	SOMNOscreen™ plus
Risk classification:	IIa
Basic-UDI-DI:	42504134SSCPKB
Intended purpose:	The SOMNOscreen™ plus is a portable device for the continuous recording of physiological signals, which serves as a polygraphy (PG) system to assist the doctor in the diagnosis of sleep disorders.

Examinations and tests performed:
390353_A211907MED_01 dated 2023-12-10
390353_A211907MED_02 SOMNOwatch plus dated 2024-06-06

Further conditions for or limitations to the validity of the certificate:
n/a

Reference to previous certificates:

Revision	Date of Issue	Certificate-ID	Description of change
n/a	n/a	n/a	n/a