



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

SOMNOmedics GmbH

Am Sonnenstuhl 63
97236 Randersacker
Germany

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Portable medical devices for sleep diagnostics, therapy control and long-term EEG, as well as non-invasive systems for cardiology diagnostics according annex.

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	390353 MR2
Certificate unique ID	170739018
Effective date	2019-10-30
Expiry date	2024-05-26
Frankfurt am Main	2019-10-30

DQS Medizinprodukte GmbH

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DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



Annex to certificate
Certificate registration No.: 390353 MR2
Certificate unique ID: 170739018
Effective date: 2019-10-30

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Device family	Device	Class
Sleep diagnostics	Mit zusätzlicher Option Blutdruck:	IIa
	SOMNO HD SOMNO HD ECO SOMNOscreen plus SOMNOWatch plus SOMNOtouch RESP SOMNOtouch PSG	
	Ohne Blutdruck:	
	SOMNOtouch RESP ECO	
Cardiology	SOMNOtouch NIBP	IIa
Long-term EEG	SOMNO HD	IIa
	SOMNOscreen plus	
	SOMNO HD ECO	
Long-term actigraphy	SOMNOWatch plus	IIa