# EU Quality Management Certificate

This is to certify that the company

## Simq GmbH

Am Schammacher Feld 37
85567 Grafing
Germany

SRN: DE-MF-000022283

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. | 534670 MDR2017Q |
| Certificate ID | 1000116096 |
| Effective date | 2024-05-02 |
| Expiry date | 2029-05-01 |
| Frankfurt am Main, | 2024-05-02 |

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-000022283
# Certificate ID: 1000116096

**Device categories and variants covered by this certificate:**

| | |
|---|---|
| Device category: | **MDA 0315 Software** |
| Product name: | Simq OSA |
| Risk classification: | IIb |
| Basic-UDI-DI: | 42623555100189 |
| Intended purpose: | The Simq OSA software provides assistance in the diagnosis and therapy by visualizing sleep-related breathing disorders. In doing so, Simq OSA depicts a numerical model of the anatomical situation of the patient's upper airway. For this purpose, Simq OSA performs a simulation of the airflow using numerical calculation methods. From this, Simq OSA provides an evaluation and visualization of fluid mechanical quantities and derived characteristic values to represent anatomical and physiological factors to assist professionals. |

**Examinations and tests performed:**
534670_A212249MED_01 dated 2023-10-04
534670_A212249MED_02 Simq OSA dated 2024-03-15

**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 |