Declaration of Conformity Simq OSA

Declaration of conformity in accordance with Annex IV of the Medical Device Regulation (MDR) 2017/745

Name, registered trade name or registered trade mark	Simq GmbH
SRN of the manufacturer	DE-MF-000022283
if available: Authorized representative	-
the address of their registered office where they can be contacted and where they are actually located	Am Schammacher Feld 37, 85567 Grafing b. Munich
A declaration that the manufacturer bears sole responsibility for issuing the EU Declaration of Conformity.	We declare under our sole responsibility the conformity with EU Regulation 2017/745.
The basic UDI-DI according to Annex VI Part C	42623555100189
Product and trade name, product code, catalog number or other unique reference allowing identification and traceability of the product covered by the EU declaration of conformity,	Simq OSA UDI-DI: 4262355510016 Software version: 1.0.x
Intended use	The product Simq OSA is indicated after initial diagnosis to support further diagnosis and therapy of sleep disordered breathing by specifying the anatomical cause. Simq OSA is not intended for sleep disordered breathing originating in the perinatal period and/or sleep disordered breathing in patients with obesity hypoventilation syndrome.

Simq GmbH
HRB Munich No. 212526
VAT ID: DE 296627257
Managing Director
MBA & Eng. Jan Hertwig

Registered office of the company
Am Schammacher Feld 37
85567 Grafing b. Munich, Germany

Minfo@cadfem-medical.com
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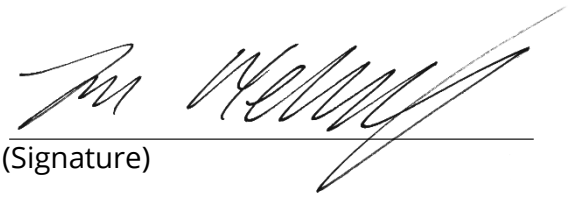
Bank details
IBAN DE05702501500027717321
BIC BYLADEM1KMS
Munich District Savings Bank
Starnberg Ebersberg

The risk class of the product according to the rules described in Annex VIII	Class IIb
An assurance that the device covered by this declaration is in conformity with this Regulation and, where applicable, other relevant Union legislation providing for the issuing of an EU declaration of conformity	is a medical device within the meaning of Article 2 (1) of (EU)2017/745 for medical devices (MDR) and complies with all applicable requirements of the Medical Device Regulation (MDR) Annex IX (EU)2017/745.
Where applicable, the name and identification number of the notified body, a description of the conformity assessment procedure carried out and identification of the certificate(s) issued	DQS Med, 0297
Place and date of issue of the declaration	Grafing b. Munich 28.06.2024
Name and function of the signatory and indication for whom and on whose behalf this person has signed, signature	Jan Hertwig, CEO

We, Simq GmbH, declare under our sole responsibility the conformity to the above mentioned Medical Device Regulation. The above-mentioned product is a medical device according to Article 2 (1) of EU Regulation 2017/745 (MDR).

It fulfills the essential safety and performance requirements according to Annex I of this regulation. Conformity has been established by means of the above-mentioned conformity assessment procedure and the relevant provisions of the Medical Devices Regulation, the state of the art and the harmonized standards have been complied with. The list of all applied standards can be requested from the manufacturer. The declaration is valid from the date of signature.

Place: Grafing near Munich
Date:28.06.2024



(Signature)

Jan Hertwig - CEO

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