EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices
Annex IX Chapter I, Section 2 and 3 and Chapter III

Registration No.:	HZ 2366874-1
Manufacturer:	SCI Health, UAB Ateities 10 LT-08303 Vilnius Lithuania
EUDAMED Single Registration No.:	LT-MF-000040441
Products:	Products of class IIa: Z12040202 PHOTOTHERAPY EQUIPMENT
Authorized representative(s):	Not applicable

Certificate history		
Revision:	Description:	Issue date:
0	Initial certification	2024-12-30

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled.
If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.:	84957428-60
Effective date:	2024-12-30
Expiry date:	2029-12-29
Issue date:	2024-12-30

Daniel Świątko
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

This certificate can be validated on https://www.certipedia.com

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

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Certificate

Quality Management System
EN ISO 13485:2016
EN ISO 13485:2016/AC:2018
EN ISO 13485:2016/A11:2021

Registration No.:	SX 2366874-1
Certificate Holder:	SCI Health, UAB Ateities 10 LT-08303 Vilnius Lithuania
Scope:	Design and development, manufacture, distribution, servicing of UV light phototherapy devices.

The Certification Body of TÜV Rheinland LGA Products GmbH certifies that the organization has established and applies a quality management system for medical devices.
Proof has been furnished that the requirements specified in the abovementioned standard are fulfilled. The quality management system is subject to yearly surveillance.

Report No.:	84957428-60
Effective date:	2024-12-30
Expiry date:	2027-12-29
Issue date:	2024-12-30

This certificate can be validated on https://www.certipedia.com

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DAkkS Deutsche Akkreditierungsstelle D-ZM-14169-01-02

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