

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

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


Daniel Świątko
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BS-MDR-091

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Product List and Application MDR

(EU) 2017/745 Annex IX and XI

Including an application according to (EU) 2023/607 -
extension of MDD certification for devices intended to be transferred to MDR



PRODUCTS:

Note: Please provide an information for all columns (also the blue columns which will not be printed).

No.	Product name or Trade Name (as listed on label)	Type of device using terminology of Basic-UDI-DI, EMDN or GMDN	Basic UDI-DI code	Medical Device Category (for all medical devices)	European Medical Device Nomenclature (EMDN) <i>Please use EMDN code 4th level (EMDN code on level 4; Letter + 6-digits; if no level 4 exists, use next upper level)</i>	Classification of product and classification rule resulting in highest risk class		Summary list of related facilities <i>(use facility codes from Facilities table, i.e IMF(1), IR&D(1))</i>	Code of EU-REP <i>(use facility No from Facilities table)</i>	Technical Documentation identifier <i>(if the TD is ready for submission)</i> or declared date of submission of the technical documentation [YYYY-MM] <i>(if the TD is not ready yet for submission)</i>	Regulation (EU) 2023/607	
						Device Class	Classification Rule including subclause according to Annex VIII				If the MDR device is intended to substitute legacy device, identification of the corresponding MDD/AIMDD device <i>Please list the devices covered by the current MDD certificate which are intended to be discontinued but to be substituted by the device as specified in columns B.</i>	MDD/AIMD Certificate(s) reference of the devices under MDR application and the notified body Identification <i>Please refer to the MDD/AIMD certificate(s) covering devices listed in columns B and/or E</i>
1	UV Tactus Phototherapy Device	Z12040202	477905397UVTactusQ8	MDA 0302 Active non-implantable devices utilising non-ionizing	Z12040202	IIa	9	IMF(1) IR&D(1)	NA	TF-B1		
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Please add or delete lines as required!