

#### **EU Quality Management System Certificate**

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX, Chapters I and III

The Notified Body of TÜV NORD CERT GmbH certifies that the manufacturer

#### modul technik GmbH Rudolf-Diesel-Straße 5 56410 Montabaur Germany

has established, documented and implemented a quality management system in accordance with Article 10, paragraph 9 of Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The conformity assessment has been carried out and successfully completed in accordance with Annex IX, Chapters I and III. The result of the assessment, references to investigations carried out, relevant common specifications and test reports are summarised in the report mentioned below. The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The validity of this certificate is based on the maintenance of the quality management system in accordance with the requirements of the Regulation and its regular surveillance by the Notified Body in accordance with Annex IX, Chapter I, Section 3. For devices of class IIb and IIa the surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

In addition to the CE marking, the identification number of the Notified Body must be affixed to the devices.

For the placing on the market of class III devices and class IIb implantable devices an additional EU technical documentation assessment certificate according to Annex IX, Chapter II is required.

Single Registration Number of the Manufacturer (SRN): DE-MF-000014647

Authorised Representative:see Section 1Limitations and Conditions:see Section 2List of Products, Risk Classification and Details:see Section 3Certificate History:see Section 4

Certificate number: 44 911 222228 Valid from: 2025-12-03
Certification decision report No.: 3535 9386 Valid until: 2030-12-02
First issued: 2025-12-03
Issue date: 2025-12-03

Edition:

4.4

TÜV NORD CERT GmbH is a Notified Body with identification number 0044

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TÜV®



## **TUV**NORD

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Certificate number: 44 911 222228

Section 1, Authorised Representative

Company name: N/A
Street, No.: -Postal Code, City: -Country: --

Section 2, Limitations and Conditions

The validity of this Certificate depends on: N/A and the following conditions: None and / or is limited to the following: N/A





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Annex IX, Chapters I and III

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Section 3, List of Products, Risk Classification and Details

#### **CLASS IIB**

Generic device group (EMDN): Z120309

Medical/Medicinal gas pipeline systems and related accessories

TD assessment report no.: 3535 9388

**Devices or groups of devices:** Medical Supply Units IV 1054 (wall-mounted)

Medical Supply Units modulux (wall-mounted)

Medical Ceiling Supply Units flex Medical Ceiling Supply Units rigid

Intended use: The medical supply units serve as a supply interface for energy

consumers and equipotential bonding sockets, for the transmission of medical gases, vacuum and AGFS, as a communication interface for light call systems and data technology, and for room, reading and examination lighting

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Certificate number: 44 911 222228

Section 4, Certificate History

Edition	Date	Action leading to revision	Certification decision report No.
1	2025-12-03	Initial certification	3535 9386

