

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

METASYS Medizintechnik GmbH
Florianistraße 3
AT-6063 Rum bei Innsbruck
Austria

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 IIIa 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): AT-MF-000014438

Authorised Representative: see Section 1

Limitations and Conditions: see Section 2

List of Products, Risk Classification and Details: see Section 3

Certificate History: see Section 4

Certificate number: 44 911 220982 Valid from: 2026-02-03

Certification decision report No.: 3541 4381 Valid until: 2029-08-08

First issued: 2024-08-09

Issue date: 2026-02-03

Edition: 4



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

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TÜV®



Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zsl.de
BS-MDR-095

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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: --
and / or is limited to the following: --

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Section 3, List of Products, Risk Classification and Details

CLASS IIA

Category of device (MDx Code)	MDN 1211 Non-active non-implantable devices for disinfecting, cleaning and rinsing
TD assessment report no.:	3534 6624
Devices or groups of devices:	GREEN&CLEAN ID N GREEN&CLEAN AD GREEN&CLEAN BR GREEN&CLEAN IK GREEN&CLEAN M2 GREEN&CLEAN SD GREEN&CLEAN SK GREEN&CLEAN WD GREEN&CLEAN WK METASAN P Planosil XO WATER DISINFECTION

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Section 4, Certificate History

Edition	Date	Action leading to revision	Certification decision report No.
1	2024-08-09	Initial certification	3534 6629
2	2024-12-05	Company name change, change notification 1	3538 4520
3	2026-01-30	Change of product range	3541 4381
4	2026-02-03	Administrative change	3541 4381