

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
Florianstraße 3
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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 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 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:	--
The validity of this EU Certificate depends on conditions and / or is limited to the following:	--

List of Products, Risk Classification and Details:	see Section 2
Certificate history:	see Section 3

Reg.-No.: 44 911 220982
Certification decision report No.: 3538 4520

Edition:	2
Issue Date:	2024-12-05
First issued:	2024-08-09
Valid from:	2024-12-05
Valid until:	2029-08-08

Essen, 05.12.2024

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

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Reg. No. 44 911 220982 Section 2, List of Products

Class IIa

Product group / Product name	Category of device (MDx)	Technical documentation assessment report number
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Disinfectants	MDN 1211	3534 6624
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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
 PlanClear
 Planosil
 ULTRADES V
 XO WATER DISINFECTION

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Reg. No. 44 911 220982 Section 3, Certificate History

Certificate History

Edition	Date	Action leading to revision	Certification decision report number
1	2024-08-09	Initial certification	3534 6629
2	2024-12-05	Company name change, change notification 1	3538 4520

