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

Laboratorium Dr. Deppe GmbH
Hooghe Weg 35
47906 Kempen
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. 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):	DE-MF-000005103
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 220522
Certification decision report No.: 3535 7347

Edition:	1
Issue date:	2024-04-11
First issued:	2024-04-11
Valid until:	2029-04-10

Essen, 2024-04-11

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

TÜV NORD CERT GmbH
Am TÜV 1, 45307 Essen
tuev-nord-cert.de
medical@tuev-nord.de

TÜV®

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

TÜVNORDGROUP

EU-Quality Management System Certificate

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

Reg. No. 44 911 220522 Section 2, List of Products

Class IIb (non implantable)

Product name	Intended purpose	Generic device group (EMDN)	Technical documentation assessment report number
Instru Extra	The product is an aldehyde- and phenol-free concentrated instrument disinfectant for the reprocessing of medical instruments using the insertion/immersion and rinsing method as well as in ultrasonic baths. It is not suitable for the final disinfection of semi-critical instruments.	D99 Disinfectants and antiseptics for medical devices - others	--
Instru Plus	The product is an aldehyde-containing, concentrated instrument disinfectant for the reprocessing of medical instruments using the insertion/immersion and rinsing method. It is particularly suitable for the final disinfection of semi-critical instruments.	D0199 Disinfectants, medical devices, aldehyds - others	3533 2633
Instru Sept AF	The product is an aldehyde- and phenol-free, liquid instrument disinfectant in concentrated form for the reprocessing of medical instruments using the insertion/immersion method. It is not suitable for the final disinfection of semi-critical instruments.	D99 Disinfectants and antiseptics for medical devices - others	3533 2568

TÜV NORD CERT GmbH
Am TÜV 1, 45307 Essen
tuev-nord-cert.de
medical@tuev-nord.de
TÜV®

Class IIb (non implantable)

Product name	Intended purpose	Generic device group (EMDN)	Technical documentation assessment report number
Instru Star rfu	The product is an aldehyde- and phenol-free, liquid instrument disinfectant in concentrated form for the reprocessing of medical instruments using the insertion/immersion method. It is not suitable for the final disinfection of semi-critical instruments.	D0901 Ammonium salts for the disinfection of medical devices	3533 2634
Instru Suc	The product is an aldehyde- and phenol-free, liquid instrument disinfectant in concentrated form for the reprocessing of medical instruments using the insertion/immersion method. It is not suitable for the final disinfection of semi-critical instruments.	D0901 Ammonium salts for the disinfection of medical devices	--

Class IIa

Product name (EMDN)		Category of device (MDx)	Technical documentation assessment report number
Beta Guard Neu	(D99)	MDN 1211, Non-active non-implantable devices for disinfecting, cleaning and rinsing	3533 2567
Beta Guard rfu	(D99)		
Immix Clean	(D0799)		
Micro Clean ECO	(D99)		
Micro Clean GT	(D99)		
Spray In Neu	(D99)		
Spray in QF	(D0701)		
Spray Off	(D99)		

TÜV NORD CERT GmbH
Am TÜV 1, 45307 Essen
tuev-nord-cert.de
medical@tuev-nord.de

EU-Quality Management System Certificate

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

Reg. No. 44 911 220522 Section 3, Certificate History

Certificate History

Edition	Date	Action leading to revision	Certification decision report number
1	2024-04-11	Initial Issuance	3535 7347

TÜV NORD CERT GmbH
Am TÜV 1, 45307 Essen
tuev-nord-cert.de
medical@tuev-nord.de