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

Hager & Meisinger GmbH

Hansemannstr. 10
41468 Neuss
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-000004966
Authorised Representative:	N/A
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.:	44 911 220 651	Edition:	2
Certification decision report No.:	3537 3262	Issue date:	2024-07-02
		First issued:	2024-03-07
		Valid until:	2029-03-06

Essen, 02.07.2024

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

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

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Reg. No. 44 911 22 0651 Section 2, List of Products

Class IIb implantable

Product name	Intended purpose	Generic device group (EMDN)	TDA report number
OKTAGON Implant	OKTAGON dental implants / OKTAGON dental Implant Infinity are intended to replace the tooth root in the mandibular and / or maxillary arches	P01020101	3533 0384
myplant bio Implant	myplant bio dental implants are intended to replace the tooth root in the mandibular and / or maxillary arches	P01020101	3533 0369
myplant two Implant	myplant two dental implants are intended to replace the tooth root in the mandibular and / or maxillary arches	P01020101	3533 0386

Class I, reusable surgical instruments

Product name / Product group name	Category of device (MDx)	report number
Surgical hand-held instruments	MDN 1208	3537 3261

For class Ir devices that are reusable surgical instruments the involvement of the notified body in the conformity assessment procedure is limited to the aspects relating to the reuse of the devices, in particular cleaning, disinfection, sterilisation, maintenance and functional testing and the related instructions for use.

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Reg. No. 44 911 220 651 Section 3, Certificate History

Certificate History

Edition	Date	Action leading to revision	Certification decision report number
01	2024-03-07	Initial certification	ZA 3535 3794
02	2024-07-02	Change notification 01.2024	ZA 3537 3262

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