EU Quality Management System Certificate

Pursuant to Regulation (EU) 2017/745 on Medical Devices,
Annex IX, Chapters I and III
Certificate number: 44 911 22 0651

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

Hager & Meisinger GmbH
Hansemannstraße 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. 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):	DE-MF-000004966
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 22 0651	Valid from:	2025-08-08
Certification decision report No.:	3537 3264	Valid until:	2029-03-06
		First issued:	2024-03-07
		Issue date:	2025-08-12
		Edition:	4

Essen, 12-08-2025

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

TÜV NORD CERT GmbH
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TÜV®

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

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Section 1, Authorised Representative

Company name:	**N/A**
Street, No.:	--
Postal Code, City:	--
Country	--
Single Registration Number:	--

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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Section 3, List of Products, Risk Classification and Details

CLASS IIB IMPLANTABLE EXEMPTED PER ART. 52(4)

Generic device group (EMDN):	**P01020101** -IMPLANTABLE PROSTHETIC AND OSTEO-SYNTHESIS DEVICES - DENTAL IMPLANTS
Assessment report no.:	ZA 3533 0384, ZA 3533 0369, ZA 3533 0386
MDA / MDN Code:	MDN 1103
Devices or groups of devices:	**Intended use:**
myplant bio Dental Implants	myplant bio dental implants are intended to replace the tooth root in the mandibular and / or maxillary arches
myplant two Dental Implants	myplant two dental implants are intended to replace the tooth root in the mandibular and / or maxillary arches
OKTAGON Dental Implants	OKTAGON dental implants are intended to replace the tooth root in the mandibular and / or maxillary arches

Generic device group (EMDN):	**P01020180** - IMPLANTABLE PROSTHETIC AND OSTEO-SYNTHESIS DEVICES - DENTAL IMPLANTS ACCESSORIES
Assessment report no.:	ZA: 3537 3263
MDA / MDN Code:	MDN 1103
Devices or groups of devices:	**Intended use:**
Prosthetic abutment systems for the fixation of dentures	Restoration of enossal dental implants during the healing phase (after implantation) and enabling subgingival and transgingival healing. Enabling a prosthetic restoration in the upper/lower jaw for divers indications on the basis of a enossal dental implant.

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Generic device group (EMDN):	**P09120604 -** IMPLANTABLE PROSTHETIC AND OSTEO-SYNTHESIS DEVICES - OSTEOSYNTHESIS NAIL-SCREW SYSTEMS
Assessment report no.:	ZA: 3537 3263
MDA / MDN Code:	MDN 1103
Devices or groups of devices:	**Intended use:**
Products for membrane fixation	The products are intended for safe fixation of apical membrane ends at the local bone to avoid micromobility of the membrane. The pins/ tacs allow the fixation of resorbable, non-resorbable and titanium reinforced membranes in the dense cortical bone or at the implant.

Generic device group (EMDN):	**P09120699** - IMPLANTABLE PROSTHETIC AND OSTEO-SYNTHESIS DEVICES - BONE FIXATION SCREWS, TENDON AND LIGAMENT SYNTHESIS SCREWS - OTHER
MDA / MDN Code:	MDN 1103
Assessment report no.:	ZA 3538 3353
Devices or groups of devices:	**Intended use:**
Products for bone fixation	The products for bone fixation are intended for the fixation and stabilization of bone segments and for the support of barrier membranes in dental surgery. The screws are used for the restoration of anatomical structures and for pre-implant vertical or horizontal augmentation.

CLASS I, REUSABLE SURGICAL INSTRUMENTS

Product name, product group name	**Report no.**
Surgical hand-held instruments	ZA 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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Section 4, Certificate History

Edition	Date	Action leading to revision	Report reference
1	2024-03-07	Initial certification	ZA 3535 3794
2	2024-07-02	Change notification 01.2024	ZA 3537 3262
3	2025-08-08	Change notification 02.2024	ZA 3537 3264
4	2025-08-12	Formal correction	ZA 3537 3264

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