ZERTIFIKAT ◆ CERTIFICATE ◆ 認證證書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Product Service

EU Quality Management System Certificate

Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapter I

Certificate No. G15 112008 0007 Rev. 00

Manufacturer:

DEEP Company SAS
ZA du Bois Saint-Pierre
38280 Janneyrias
FRANCE

SRN Manufacturer - FR-MF-000009485

The quality management system has been evaluated in accordance with Regulation (EU) 2017/745, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.
The certified quality management system is subject to periodical surveillance.

If class I devices in sterile conditions, with measuring function, or reusable surgical instruments are covered by this certificate, the audit was limited to the respective aspects relating to
- establishing, securing, and maintaining sterile conditions,
- conformity of the devices with the metrological requirements,
- reuse of the device, in particular cleaning, disinfection, sterilization, maintenance and functional testing and the related instructions for use.

If class IIa or class IIb devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.
If class III or class IIb implantable devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G15 112008 0007 Rev. 00

Report No.: ITA1870281
Valid from: 2025-08-08
Valid until: 2030-08-07

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-08-08

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Certificate No. G15 112008 0007 Rev. 00

Classification:	Class IIb
Device Group:	P010201 - DENTAL IMPLANTS AND ACCESSORIES
Intended Purpose:	Dental implants are intended to replace the root of an absent tooth, in the mandible as in the maxilla,caused by accidental or pathological loss, extraction or agenesis, when the other medical and surgical possibilities have been considered less appropriate.
Classification:	Class IIb
Device Group:	P010201 - DENTAL IMPLANTS AND ACCESSORIES
Intended Purpose:	Abutments are intended to support the overdenture and ensure its junction with the implant in case of the prosthetic rehabilitations that range from replacing one single tooth to an entire arch of bridgework, as well as retentive elements for overdenture applications.
Classification:	Class IIb
Device Group:	P010201 - DENTAL IMPLANTS AND ACCESSORIES
Intended Purpose:	Healing abutments are intended to prepare gingival tissues during the healing phase in case of the prosthetic rehabilitations that range from replacing one single tooth to an entire arch of bridgework, as well as retentive elements for overdenture applications.
Classification:	Class IIb
Device Group:	P010201 - DENTAL IMPLANTS AND ACCESSORIES
Intended Purpose:	The cover screw is intended to be connected to the implant in order to protect the internal connection during the healing phase.
Classification:	Class IIa
Device Group:	MDN 1208 - Non-active non-implantable instruments
Classification:	Class I
Device Group:	L15 - ODONTOSTOMATOLOGY INSTRUMENTS, REUSABLE
Device Properties:	MDS 1006 - Reusable surgical instruments
The validity of this certificate depends on conditions and/or is limited to the following:	\

Revision History:

Rev.	Dated	Report	Description
00	2025-08-08	ITA1870281	Initial issuance

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