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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 (MDR)

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

No. G10 109871 0003 Rev. 00

Manufacturer:

HPF S.r.l.
Via A. Marcuzzi, 2/5
33034 Fagagna (UD)
ITALY

SRN Manufacturer - IT-MF-000017541

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the 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 Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. 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.
All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 109871 0003 Rev. 00

Report No.: ITA1938935

Valid from: 2023-10-19
Valid until: 2028-10-18

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-10-19

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123
TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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Classification:	Class IIa
Device Group:	L090401 - ORTHOPAEDIC SURGERY OSTEOTOMES, REUSABLE L091101 - ORTHOPAEDIC PROSTHESES AND TRAUMATOLOGICAL IMPLANTS EXTRACTORS, REUSABLE L091102 - ORTHOPAEDIC PROSTHESES REAMERS AND BURS, REUSABLE L091104 - ORTHOPAEDIC PROSTHESES POSITIONERS, REUSABLE L091199 - ORTHOPAEDIC PROSTHETICS INSTRUMENTS, REUSABLE - OTHER L091399 - ORTHOPAEDIC SURGERY FORCEPS, REUSABLE - OTHER L0916 - ORTHOPAEDIC SURGERY BURS AND TIPS, REUSABLE L0919 - ORTHOPAEDIC AND TRAUMATOLOGICAL SURGERY INSTRUMENT KITS, REUSABLE L0922 - ORTHOPAEDIC SURGERY GUIDES, REUSABLE L098001 - ORTHOPAEDIC AND TRAUMATOLOGICAL SURGERY MANDRELS, REUSABLE L0999 - ORTHOPAEDIC AND TRAUMATOLOGICAL SURGERY INSTRUMENTS, REUSABLE - OTHER L26 - SURGICAL SCREWDRIVERS, REUSABLE P091301 - ORTHOPAEDIC IMPLANT REAMERS, SINGLE-USE P091303 - ORTHOPAEDIC IMPLANT DRILL BITS, SINGLE-USE V060101 - ORTHOPAEDIC PROSTHESES TESTING DEVICES
Intended Purpose:	\
The validity of this certificate depends on conditions and/or is limited to the following:	\

Revision History:

Rev.	Dated	Report	Description
00	2023-10-19	ITA1938935	Initial issuance

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