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 053618 0028 Rev. 02

Manufacturer:

ZHERMACK S.p.A
trading as ZK SPA
trading as ZRK SPA
trading as ZAC SPA
Via Bovazecchino 100
45021 Badia Polesine (RO)
ITALY

SRN Manufacturer - IT-MF-000011215

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, 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:G10 053618 0028 Rev. 02

Report No.:	ITA1978808
Preceding Certificate No.:	G10 053618 0028 Rev. 01
Valid from:	2025-02-12
Valid until:	2026-10-20
Date of Initial Issuance:	2021-10-21

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2025-02-12

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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(Class IIa and Class IIb Devices)

No. G10 053618 0028 Rev. 02

Classification:	Class IIa
Device Group:	Q010201 - DENTAL IMPRESSION MATERIALS
Intended Purpose:	\

Classification:	Class IIa
Device Group:	D0799 - ALCOHOLS FOR THE DISINFECTION OF MEDICAL DEVICES - OTHER
Intended Purpose:	\

Classification:	Class IIa
Device Group:	D0902 - ASSOCIATED AMMONIUM SALTS FOR THE DISINFECTION OF MEDICAL 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	2021-10-21	ITA1468758	-
01	2024-06-28	ITA1482964425	Amended: Change of certificate holder's data
02	2025-02-12	ITA1978808	Supplemented: Device(s)/group of device(s) added

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