



America

CERTIFICATE

No. QS6 053618 0026 Rev. 02

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

Certification Mark:



Scope of Certificate: Design and Development, Production and Distribution of Silicones and Alginates for Impressions, Disinfectants for Medical Devices and Acrylic Resins

Standard(s): ISO 13485:2016

Regulatory Authority(ies): Australia TGA, Brazil ANVISA, Health Canada, Japan MHLW / PMDA, USA FDA. See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. For details and certificate validity see:

www.tuvsud.com/ps-cert?q=cert:QS6_053618_0026_Rev_02

TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: F001374
Report No.: ITA1482964425
Effective Date: 2024-05-21
Expiry Date: 2027-05-20

Page 1 of 2

Date of Issue: 2024-05-09

(Renee Walker)

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Regulatory Requirements: Audit/Certification Criteria

Australia

Therapeutic Goods (Medical Devices) Regulations 2002
 - Schedule 3, Part 1 (excluding Part 1.6) – Full Quality Assurance Procedure

Brazil

- RDC ANVISA n. 665/2022 - Good Manufacturing Practices
 - RDC ANVISA n. 551/2021
 - RDC ANVISA n. 67/2009 - Vigilance

Canada

- Medical Device Regulations – Part 1- SOR 98/282

Japan

- MHLW Ministerial Ordinance No. 169 (2004), as amended by MHLW Ministerial Ordinance No.60 (2021)
 - Japan PMD Act (as applicable)

United States

- 21 CFR Part 803
 - 21 CFR Part 806
 - 21 CFR Part 807 – Subparts A to D
 - 21 CFR Part 820

Facility(ies):

ZHERMACK S.p.A trading as ZK SPA trading as ZRK SPA trading as ZAC SPA

Via Bovazecchino 100, 45021 Badia Polesine (RO), ITALY

Facility Scopes:

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Page 2 of 2

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