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

America

# C E R T I F I C A T E

## No. QS6 053618 0026 Rev. 01

**Certificate Holder:** **ZHERMACK S.p.A**
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, USA FDA, MHLW / PMDA. 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. Validity of this certificate can be obtained by visiting the website www.tuvsud.com/ps-cert
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

**REPs Facility ID:** **F001374**

**Effective Date:** **2021-05-21**

**Expiry Date:** **2024-05-20**


**Date of Issue:** 2021-06-18

( Tina Israel )
Manager, US Certification Body,
Medical and Health Services

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MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

# C E R T I F I C A T E

## No. QS6 053618 0026 Rev. 01

**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. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009

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

**Japan**
- MHLW Ministerial Ordinance 169, Article 4 to Article 68
- PMD Act

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

**Facility Scopes:** Design and Development, Production and Distribution of Silicones and Alginates for Impressions, Disinfectants for Medical Devices and Acrylic Resins
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