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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

CERTIFICATE

No. QS6 063353 0010 Rev. 02

Certificate Holder: **BIOKOSMES S.r.l.**
Via dei Livelli,1
23842 Bosisio Parini (LC)
ITALY

Certification Mark:

Scope of Certificate: **Design, Development and Manufacture of Liquids, Sprays and Semi-Solid Preparations for Application in Skin, Gynecological, Proctological, Otolaryngologic, Mucosal Field and for Wound Care; Design, Development and Manufacture for Third Parties such as Liquids, Sprays and Semi-Solid Preparations for Application in Skin, Gynecological, Proctological, Otolaryngologic, Mucosal Field and for Wound Care; Manufacture for Third Parties of Preparation, Washing and Decontamination of Tissues for Transplantation**

Standard(s): **ISO 13485:2016**

Regulatory Authority(ies): **Australia TGA, Brazil ANVISA, Health Canada, 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 063353 0010 Rev. 02
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F002656**
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Date of Issue: 2023-10-10

(Renee Walker)
Director, US Certification Body, MHS

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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

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

Facility(ies): **BIOKOSMES S.r.l.**
Via dei Livelli,1, 23842 Bosisio Parini (LC), ITALY

Facility Scopes: Design, Development and Manufacture of Liquids, Sprays and Semi-Solid Preparations for Application in Skin, Gynecological, Proctological, Otolaryngologic, Mucosal Field and for Wound Care; Design, Development and Manufacture for Third Parties such as Liquids, Sprays and Semi-Solid Preparations for Application in Skin, Gynecological, Proctological, Otolaryngologic, Mucosal Field and for Wound Care; Manufacture for Third Parties of Preparation, Washing and Decontamination of Tissues for Transplantation
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