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

America

CERTIFICATE

No. QS6 110417 0004 Rev. 02

Certificate Holder: **QUESTALPHA GmbH & Co. KG**
Im Heerfeld 7
35713 Eschenburg
GERMANY

Certification Mark:

Scope of Certificate: **Design and Development, Production and Distribution of Sterile and Non-Sterile Medical Absorbent Devices and Provision of Medical Absorbent Components**

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

Regulatory Authority(ies): **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 110417 0004 Rev. 02
TÜV SÜD America Inc. is an MDSAP Recognized Auditing Organization.

REPs Facility ID: **F005363**
Report No.: **713334551**
Effective Date: **2024-10-03**
Expiry Date: **2027-10-02**

Date of Issue: 2024-09-30

(Renee Walker)
Director, US Certification Body, MHS

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

MDSAP
MEDICAL DEVICE SINGLE AUDIT PROGRAM

TÜV SÜD America

C E R T I F I C A T E

No. QS6 110417 0004 Rev. 02

Regulatory Requirements: **Audit/Certification Criteria**

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): **QUESTALPHA GmbH & Co. KG**
Im Heerfeld 7, 35713 Eschenburg, GERMANY

Facility Scopes: Design and Development, Production and Distribution of Sterile and Non-Sterile Medical Absorbent Devices and Provision of Medical Absorbent Components
REPs Facility ID: F005363

Date of Issue: 2024-09-30

(Renee Walker)
Director, US Certification Body, MHS

TÜV®

TÜV SÜD America, Inc. • 401 Edgewater Place Suite #500 • Wakefield • MA 01880 • USA • www.tuvsud.com