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

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 016389 0029 Rev. 01

Manufacturer:

VBM Medizintechnik GmbH
Einsteinstrasse 1
72172 Sulz a. N.
GERMANY

SRN Manufacturer - DE-MF-000005907

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 and certification regulation of TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 016389 0029 Rev. 01

Report No.: 713254954

Preceding Certificate No.: G10 016389 0029 Rev. 00

Valid from: 2023-08-03
Valid until: 2026-08-23

Date of Initial Issuance: 2021-08-24

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2023-08-03

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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Classification:	Class IIa
Device Group:	R010202 - LARYNGEAL TUBES
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	R010380 - ENDOTRACHEAL TUBES - ACCESSORIES
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	R010699 - PERCUTANEOUS TRACHEOSTOMY KITS - OTHER
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	R020101 - STANDARD BREATHING CIRCUITS
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	R020201 - FIXED CATHETER MOUNTS
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	R020202 - MOBILE CATHETER MOUNTS
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	R0203 - ANAESTHESIA AND RESUSCITATION CONNECTORS
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	R030101 - VENTILATION MASKS
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	R030202 - MANUALLY OPERATED VENTILATION BALLOONS
Intended Purpose:	./.

Classification:	Class IIa
Device Group:	Z12139006 - PNEUMATIC TOURNIQUETS
Intended Purpose:	./.

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The validity of this certificate depends on conditions and/or is limited to the following: -none-

Revision History:

Rev.	Dated	Report	Description
00	2021-08-24	713191553	-
01	2023-08-03	713254954	Supplemented: Device(s)/group of device(s) added

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