Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex V
(Devices in class I in sterile conditions, sterilised systems or procedure packs)

No. G2S 016389 0022 Rev. 01

Manufacturer	**VBM Medizintechnik GmbH** Einsteinstr. 1 72172 Sulz a. N. GERMANY
Facility(ies):	VBM Medizintechnik GmbH Einsteinstr. 1, 72172 Sulz a. N., GERMANY
Product Category(ies):	**Tube Fixations with accessories, Esmarch Bandages, Insertion guides for tracheal tubes and gastric tubes**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with securing and maintaining sterile conditions of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.:	713137731_3
Valid from:	2018-10-21
Valid until:	2023-10-20

Date, 2018-10-18

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder
für Gesundheitsschutz
bei Arzneimitteln und
Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

Product Service

EC Certificate

Production Quality Assurance System
Directive 93/42/EEC on Medical Devices, Annex V
(Devices in class I with measuring function)

No. G2M 016389 0018 Rev. 01

Manufacturer:

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

Facility(ies):

VBM Medizintechnik GmbH
Einsteinstr. 1, 72172 Sulz a. N., GERMANY

Product Category(ies):

Cuff-Pressure-Gauges with accessories

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for the manufacture in accordance with MDD Annex V. This quality assurance system covers those aspects of manufacture concerned with the metrological requirements of the respective devices / device categories and conforms to the requirements of this Directive. It is subject to periodical surveillance. See also notes overleaf.

Report No.: 713137731_2

Valid from: 2018-10-21
Valid until: 2023-10-20

Date, 2018-10-10

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
ZLG-BS-244.10.08

TÜV SÜD Product Service

EC Certificate

Full Quality Assurance System
Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 016389 0017 Rev. 01

Manufacturer:

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

Facility(ies):

VBM Medizintechnik GmbH
Einsteinstr. 1, 72172 Sulz a. N., GERMANY

Product Category(ies):

Tourniquet Systems and Pressure Infusors with cuffs, Medical Devices for Trans Tracheal Ventilations, Laryngeal Tubes, Respiration Sets, Respiration accessories (except class I), Rectal Tampon by Roche (RTR)

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.: 713137731_1

Valid from: 2018-10-21
Valid until: 2023-10-20

Date, 2018-10-18

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany