B|BRAUN

B. Braun Melsungen AG
Sparte Hospital Care
Marketing & Sales

34209 Melsungen
Deutschland

Ansprechpartner: Jörg Griesel

Telefon: 05661 71-47 29
Fax: 05661 71-47 29
E-Mail: joerg.griesel@bbraun.com
Internet: http://www.bbraun.de

Datum: 08. January 2019

Digitally signed by Dicusar Vladimir
Date: 2019.02.14 15:23:51 EET
Reason: MoldSign Signature
Location: Moldova

Authorization Letter

Dear Sirs,

We, **B. Braun Melsungen AG, Carl-Braun-Strasse 1, 34212 Melsungen, Germany**, herewith officially authorize

Messrs. "TETIS International " Ltd. – Calea Orheiului Str. 103/3, 2020 Chisinau, Republic of Moldova

to represent the range of Hospital Care products of B. Braun Melsungen AG in the tenders for the state purchases of the medical equipment which will take place within the year 2019 on the territory of Republic of Moldova.

The Authorization Letter is valid until December 31st, 2019.

B. Braun Melsungen AG

i.V.

B. Braun Melsungen AG i. A.
B|BRAUN

J. Griesel
Vice President/Regional Head
Hospital Care Eastern Europe 3d

Germany

F. Haag
Assistant to Regional Heads Global Marketing & Sales Department
Hospital Care

ZERTIFIKAT ◆ CERTIFICATE ◆ 認証書 ◆ СЕРТИФИКАТ ◆ CERTIFICADO ◆ CERTIFICAT

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 15 04 12974 420

Manufacturer:

B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Product Category(ies):

Active medical devices for fluid management:
- Volumetric infusion pumps
- Infusion syringe pumps
- Elastomeric Pumps
- Control & organisation units and systems made out of it
- Irrigation Pump and Accessories
Enteral feeding pumps
Devices for nerve stimulation

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.: 713060155

Valid from: 2015-05-20
Valid until: 2019-10-27

Date, 2015-05-21

Hans-Heiner Junker

609460

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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 15 04 12974 420

Facility(ies):

B. Braun Melsungen AG
Schwarzenberger Weg 73-79, 34212 Melsungen, GERMANY

B.Braun Melsungen AG
Pfieffewiesen, 34212 Melsungen, GERMANY

B. Braun Medical Industries Sdn. Bhd.
Bayan Lepas Free Industrial Zone, 11900 Penang, MALAYSIA

B. Braun Melsungen AG
Carl-Braun-Str. 1, 34212 Melsungen, GERMANY

B. Braun Melsungen AG
Am Buschberg 1, 34212 Melsungen, GERMANY

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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 18 04 12974 455

Manufacturer:

B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Product Category(ies):

Non-active medical devices (sterile and non-sterile) for:
- Injection, Infusion, transfusion and nutrition
- Anaesthesia, emergency, intensive and home care
- Disinfecting, cleaning, rinsing
- Irrigation
- Cryotherapy
- Configued customized sets
- Medical devices for wound care
- Medical Gloves
- Sterile Solutions

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.: 713128918

Valid from: 2018-05-11
Valid until: 2023-05-01

Date, 2018-05-11

Stefan Preiß

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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 18 04 12974 455

Facility(ies):

B. Braun Melsungen AG
Carl-Braun-Str. 1, 34212 Melsungen, GERMANY

ALMO-Erzeugnisse Erwin Busch GmbH
Große Allee 84, 34454 Bad Arolsen, GERMANY

B. Braun Medical SAS
13 rue Croix Comtesse, 28402 Nogent-le-Rotrou, FRANCE

B. BRAUN Vietnam Co., Ltd.
170 La Thanh Road, Dong Da District, 63000 Hanoi, VIETNAM

B. Braun Medical Kft Production Division
Déli-Külhatár út 2-4, 3200 Gyöngyös, HUNGARY

B. Braun Medical Inc.
901 Marcon Boulevard, Allentown PA 18109-9341, USA

B. Braun Melsungen AG
Neue Stiftingtalstrasse 2, 8010 Graz, AUSTRIA

B.Braun Aesculap Japan Co., Ltd. Tochigi Factory - Hospital Care
285 Ogaki, Tsuga-machi, Tochigi-shi, Tochigi, 328-0101 JAPAN

B. Braun Medical Industries Sdn. Bhd.
Bayan Lepas Free Industrial Zone, 11900 Penang, MALAYSIA

B. Braun Medical AG
Hauptstraße 39, 6182 Escholzmatt, SWITZERLAND

B. BRAUN Vietnam Co., Ltd.
Thanh Oai Industrial Complex, Thanh Oai District, 156800 Hanoi, VIETNAM

B. Braun Melsungen AG OPM
Carl-Braun-Straße 1, 34212 Melsungen, GERMANY

B. Braun Melsungen AG OPM
Schwarzenberger Weg 73-79, 34212 Melsungen, GERMANY

B. Braun Medical AG
Seesatz 17, 6204 Sempach, SWITZERLAND

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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 18 04 19717 028

Manufacturer:

B. Braun Avitum Italy S.p.A.
Via XXV Luglio, 11
41037 Mirandola (MO)
ITALY

Facility(ies):

B. Braun Avitum Italy S.p.A.
Via XXV Luglio, 11, 41037 Mirandola (MO), ITALY

Product Category(ies):

Containers for Solutions;
Accessories for Dialysis, Nutrition, Infusion and Apheresis;
Sets for Infusion and Irrigation

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.: 713130943

Valid from: 2018-09-02
Valid until: 2023-09-01

Date, 2018-07-10

Stefan Preiß

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Product Service

EC Certificate

EC Design-Examination Certificate

Directive 93/42/EEC on Medical Devices (MDD), Annex II (4)
(Devices in Class III)

No. G7 17 11 12974 445

Manufacturer: **B. Braun Melsungen AG**
Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Product: **Catheters for Single Use**
Central Venous Catheter Sets

Model(s): CERTOFIX®

Parameters: One to five lumen cava catheter set for the catheterization of the superior vena cava using Seldinger technique

- As specified in the attachment to this certificate -

The Certification Body of TÜV SÜD Product Service GmbH declares that a design examination has been carried out on the respective devices in accordance with MDD Annex II (4). The design of the devices conforms to the requirements of this Directive. For marketing of these devices an additional Annex II certificate is mandatory. See also notes overleaf

Report no.: 713106615

Valid from: 2018-01-17
Valid until: 2021-01-16

Date, 2018-01-15

Stefan Preiß

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TÜV®

Certofix®
One to five lumen cava catheter set for the catheterization of the superior vena cava using Seldinger technique

Composition of the "Product Name":

[Description of the Catheter] [Needle Type] [Catheter outer diameter] [Catheter length]

e.g. (with square brackets for visualization)
[CERTOFIX® DUO] [S] [7][30]:

CERTOFIX® DUO	Standard Catheter with two lumen
S	Seldinger Needle
7	7F outer diameter
30	30cm catheter length

Description of the Catheter	
Standard, incl. HF:	Certofix® Mono Certofix® Duo Certofix® Duo HF Certofix® Trio Certofix® Trio HF Certofix® Quattro Certofix® Quinto
Paed:	Certofix® Mono Paed Certofix® Duo Paed Certofix® Trio Paed
Econoline:	Certofix® Mono Certofix® Duo Certofix® Trio
Protect, incl. Protect HF:	Certofix® Protect Mono Certofix® Protect Duo Certofix® Protect Duo HF Certofix® Protect Trio Certofix® Protect Trio HF Certofix® Protect Quattro Certofix® Protect Quinto
Safety	Certofix® Safety Mono Certofix® Safety Duo Certofix® Safety Trio Certofix® Safety Quattro Certofix® Safety Quinto

Needle Types	
S	Seldinger Needle / Seldinger Safety Needle (for Safety Set)
V	Valve Needle
"No letter"	Indicates Econoline Set with Seldinger Needle

Catheter outer diameter:		
Type	Number according Product Name	Dimension
Mono	2; 3; 4	18 Gauge (1,4mm); 16 Gauge (1,7mm); 14 Gauge (2,1mm)
Duo	7	7 French (2,4mm)
Duo HF	7; 9; 12	7 French (2,4mm); 9 French (3,0mm); 12 French (4,0mm)
Trio	7	7 French (2,4mm)
Trio HF	12	12 French (4,0mm)
Quattro	8	8 French (2,7mm)
Quinto	12	12 French (4,0mm)
Mono Paed	1	22 Gauge (0,9mm)
Duo Paed	4; 5	4 French (1,4mm); 5 French (1,7mm)
Trio Paed	5	5 French (1,7mm)

Catheter length [cm]:	
Standard (incl. HF), EconoLine, Protect (incl. HF), Safety:	
Effective catheter length:	15; 20; 30
Paed:	
Effective catheter length:	8; 10; 13; 20

Accessory in the set (depends on set configuration):	
Product description	**Product name**
Standard (including HF) • Catheter • Slide clamp (white) • Safsite valves • Guide wire with dispenser • Movable fixation (base & clip) (with fixation wings) • Stationary fixation (base & clip) (only 12F catheters) • Seldinger Needle (S-Sets) / Valve Needle (V-Sets) • Dilator • Scalpel • Syringe • ECG connection cable	Omnifix®
Mono Paed (see Standard with following exception) • Steel stylet instead of Guide wire • Statlock fixation • Only Seldinger Needle • Infusion extension line • Three-way stopcock	Discofix®
Duo / Trio Paed (see Standard with following exception) • Statlock fixation • Only Seldinger Needle	
EconoLine (see Standard with following exception) • IN Stopper instead of Safsite valves • Only Seldinger Needle • No Scalpel • No Syringe • No ECG connection cable	

Protect incl. Protect HF (see Standard with following exception) • Catheter with Protect coating instead of Catheter • Slide clamp green instead of Slide clamp (white) • Only Valve Needle **Safety** (see Standard with following exception) • Safety Scalpel instead of Scalpel • Seldinger Safety instead of Seldinger Needle	

Attachment for Certificate no G7 17 11 12974 445
valid from 2018-01-17 Project No. 713106615

Above referenced Certofix ® catheters can be combined with following accessories for the assembly **of Customer Kits (ProSet):**

Product description	Product name
(Hypodermic) needle	Sterican®
Syringe	Omnifix®, Injekt
Three-way stopcock	Discofix®
Filter and Filter straw	
Swab	
Gauze / gauze pads	
Compresses	
Prep sponge	
Pincer	
Clamp	
Trays	
Gloves	Vasco®
Adhesives / Plasters	Askina®
Drape	
Fenestrated drape	
Sutures	
Ampoule sodium chloride	
Combidyn pressure tubing lines	
OP smock	
ECG connection cable	
Alphacard system	
Special label's in the set	
Paper towel	
Tubing systems	
Ultrasound gel	
Ultrasound cover bag	
Safeflow	
Blood lancet	
Catheter polster	
Needle foam	
Backflow valve	

Munich, MHS-CRT, 2017-01-15

Stefan Preiß

DAkkS
Deutsche
Akkreditierungsstelle
D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 019717 0030 Rev. 00

Holder of Certificate: **B. Braun Avitum Italy S.p.A.**
Via XXV Luglio, 11
41037 Mirandola (MO)
ITALY

Certification Mark:

TÜV SÜD
EN ISO 13485
tuv-sud.com/ps-cert

Scope of Certificate: **Design and Development, Production and Distribution of Non-Active Medical Devices for Extracorporeal Blood Treatment (Hemodialysis, Acute Dialysis, Apheresis); Design and Development, Production of Non-Active Medical Devices for Transfusion, Nutrition, Irrigation and Arthroscopy; Distribution and Servicing of Active Medical Devices for Extracorporeal Blood Treatment and Nutrition; Production and Distribution of Concentrates for Hemodialysis**

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713124436

Valid from: 2018-10-24
Valid until: 2021-07-31

Date, 2018-10-24

Stefan Preiß

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A4 / 07.17

DAkkS
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D-ZM-11321-01-00

TÜV SÜD
Product Service

Certificate

No. Q5 019717 0030 Rev. 00

Applied Standard(s): EN ISO 13485:2016
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2016)
DIN EN ISO 13485:2016

Facility(ies): B. Braun Avitum Italy S.p.A.
Via XXV Luglio, 11, 41037 Mirandola (MO), ITALY

Supplement to Quality System Certificate

B. Braun Avitum Italy S.p.A.
Via XXV Luglio, 11
41037 Mirandola (MO), ITALY

for the facility

B. Braun Avitum Italy S.p.A.
Via XXV Luglio, 11
41037 Mirandola (MO), ITALY

The quality system certified as stated above additionally fulfills the applicable requirements of **EN ISO 11135:2014 – Sterilization of health care products – Ethylene oxide** - as documented in the audit report no. 713124436.

The assessment was performed by auditors authorized under TÜV SÜD Product Service GmbH procedures. The audit team included an auditor authorized for sterilization.

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Product Service

CERTIFICATE

No. Q2N 17 11 12974 447

Holder of Certificate: **B. Braun Melsungen AG**
Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Facility(ies):
B. Braun Medical Kft Production Division
Déli-Külhatár út 2-4, 3200 Gyöngyös, HUNGARY

Certification Mark:

tuv-sud.com/ps-cert

Scope of Certificate: **Production of tubing sets and assemblies for sterile medical devices for fluid, blood and gas management, including moulding, extrusion, welding, heat forming, gluing, printing and packing under controlled conditions. Products include: blood lines, suction and drainage, urology, catheterization, ventilation, nutrition, transfusion/infusion/rinsing and configured customised sets.**

Applied Standard(s):
EN ISO 13485:2012 + AC:2012
Medical devices - Quality management systems - Requirements for regulatory purposes
(ISO 13485:2003 + Cor. 1:2009)
DIN EN ISO 13485:2012
Upgrade required until 2019-03-31

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system (excluding subclause 7.3), which meets the requirements of the listed standard(s). See also notes overleaf.

Report No.: 713120812

Valid from: 2018-02-28
Valid until: 2021-02-27

Date, 2018-01-17

Stefan Preiß

Page 1 of 1

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D-ZM-11321-01-00

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