

ZERTIFIKAT ♦ CERTIFICATE ♦ 認 証 証 書 ♦ CERTIFICADO ♦ CERTIFICAT



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**

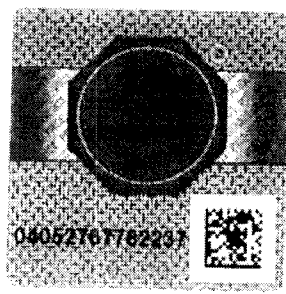
Model(s): **CERTOPIX®**

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

S. Preiß
Stefan Preiß

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

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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
<p>Standard (including HF)</p> <ul style="list-style-type: none"> • 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®
<p>Mono Paed (see Standard with following exception)</p> <ul style="list-style-type: none"> • Steel stylet instead of Guide wire • Statlock fixation • Only Seldinger Needle • Infusion extension line • Three-way stopcock 	Discofix®
<p>Duo / Trio Paed (see Standard with following exception)</p> <ul style="list-style-type: none"> • Statlock fixation • Only Seldinger Needle 	
<p>EconoLine (see Standard with following exception)</p> <ul style="list-style-type: none"> • IN Stopper instead of Safsite valves • Only Seldinger Needle • No Scalpel • No Syringe • No ECG connection cable 	

<p>Protect incl. Protect HF (see Standard with following exception)</p> <ul style="list-style-type: none">• Catheter with Protect coating instead of Catheter• Slide clamp green instead of Slide clamp (white)• Only Valve Needle <p>Safety (see Standard with following exception)</p> <ul style="list-style-type: none">• Safety Scalpel instead of Scalpel• Seldinger Safety instead of Seldinger Needle	
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Above referenced Certofix® catheters can be combined with following accessories for the assembly of Customer Kits (ProSet):

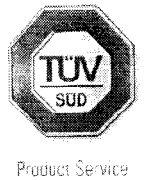
Product description	Product name
(Hypodermic) needle	Sterican®
Syringe	Omnifix®, Injekt
Three-way stopcock	Discofix®
Filter and Filter straw	
Swab	
Gauze / gauze pads	
Compresses	
Prep sponge	
Pincer	
Clamp	
Trays	
Gloves	Vasco®
Adhesives / Plasters	Askina®
Drape	
Fenestrated drape	
Sutures	
Ampoule 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

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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:

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
Stefan Preiß



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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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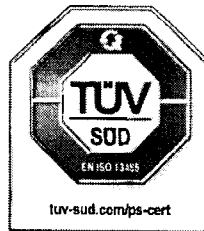
Product Service

Certificate

No. Q5 012974 0590 Rev. 00

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

Certification Mark:



Scope of Certificate: Design and Development, Production, Installation, Servicing, Sales and Distribution of:

- 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
 - Configured customized sets
- Non-active medical devices (sterile and non-sterile):
 - Medical devices for wound care
 - Medical Gloves
 - Sterile solutions
- In-vitro Diagnostics: devices for blood glucose measurement and urine collection
- Active medical devices for:
 - Fluid management
 - Nerve Stimulation
 - Enteral Feeding
 - Irrigation

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.: 713127867

Valid from: 2018-11-09

Valid until: 2021-10-20

Date, 2018-11-09

Stefan Preiß

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

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



Certificate

No. Q5 012974 0590 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 Melsungen AG
Schwarzenberger Weg 73-79, 34212 Melsungen, GERMANY
- B. Braun Melsungen AG
Pfieffewiesen, 34212 Melsungen, GERMANY
- B. Braun Melsungen AG Werk Spangenberg
Dörnbach 10, 34286 Spangenberg, GERMANY
- B. Braun Melsungen AG Werk E
Schwarzenberger Weg 21-27, 34212 Melsungen, GERMANY
- B. Braun Melsungen AG OPM
Schwarzenberger Weg 73-79, 34212 Melsungen, GERMANY
- B. Braun Melsungen AG OPM
Carl-Braun-Straße 1, 34212 Melsungen, GERMANY
- B. Braun Melsungen AG
Neue Stiftingtalstrasse 2, 8010 Graz, AUSTRIA
- B. Braun Melsungen AG
Carl-Braun-Str. 1, 34212 Melsungen, GERMANY
- B. Braun Melsungen AG Werk A und K
Carl-Braun-Str. 1, 34212 Melsungen, GERMANY

Parameters:

-/-