



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

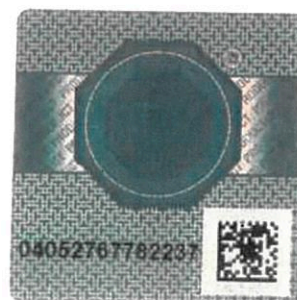
- As specified in the attachment to this certificate -

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

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 Syringe Three-way stopcock Filter and Filter straw Swab Gauze / gauze pads Compresses Prep sponge Pincer Clamp Trays Gloves Adhesives / Plasters 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	Sterican® Omnifix®, Injekt Discofix® Vasco® Askina®

Munich, MHS-CRT, 2017-01-15



Stefan Preiß