

Konformitätserklärung Declaration of Conformity

Wir

We

**B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany**

erklären in eigener Verantwortung,
dass das/die Produkt/e

hereby declare in our own responsibility
that the product/s

Certofix®

Certofix®

**Certofix® Mono,
Certofix® Mono Paed,
Certofix® protect Mono,
Certofix® Safety Mono**

**Certofix® Mono,
Certofix® Mono Paed,
Certofix® protect Mono,
Certofix® Safety Mono**

**Certofix® Duo,
Certofix® Duo HF,
Certofix® Duo Paed,
Certofix® protect Duo,
Certofix® protect Duo HF,
Certofix® Safety Duo**

**Certofix® Duo,
Certofix® Duo HF,
Certofix® Duo Paed,
Certofix® protect Duo,
Certofix® protect Duo HF,
Certofix® Safety Duo**

**Certofix® Trio,
Certofix® Trio HF,
Certofix® Trio Paed,
Certofix® protect Trio,
Certofix® protect Trio HF,
Certofix® Safety Trio**

**Certofix® Trio,
Certofix® Trio HF,
Certofix® Trio Paed,
Certofix® protect Trio,
Certofix® protect Trio HF,
Certofix® Safety Trio**

**Certofix® Quattro,
Certofix® protect Quattro,
Certofix® Safety Quattro**

**Certofix® Quattro,
Certofix® protect Quattro,
Certofix® Safety Quattro**

**Certofix® Quinto,
Certofix® protect Quinto,
Certofix® Safety Quinto**

**Certofix® Quinto,
Certofix® protect Quinto,
Certofix® Safety Quinto**

Zentrale Venenkatheter
(Artikelnummern siehe Anlage I)

Central Venous Catheters
(article numbers see attachment I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen

is/are in compliance with the following directive

Effective

Richtlinie 93/42/EWG des Rates vom 14. Juni
1993
über Medizinprodukte
geändert durch Richtlinie 2007/47/EG

Konformitätsbewertungsverfahren
nach Anhang II
der oben genannten Richtlinie

Klassifizierung
gemäß Anhang IX der
oben genannten Richtlinie
Klasse III

Benannte Stelle
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123

Datum der ersten CE-Kennzeichnung

Certofix® Mono	1997-01
Certofix® Duo	1996-01
Certofix® Trio	1996-01
Certofix® Quattro	2001-10
Certofix® Quinto	1998-07

Gültig bis
2024-05-26

Council Directive 93/42/EEC of 14th June
1993
concerning Medical Devices
amended by Directive 2007/47/EC

Conformity Assessment Procedure
according to annex II
of the Council Directive named above

Classification
according to annex IX of the
Council Directive named above
Class III

Notified Body
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123

Date of first CE-marking

Certofix® Mono	1997-01
Certofix® Duo	1996-01
Certofix® Trio	1996-01
Certofix® Quattro	2001-10
Certofix® Quinto	1998-07

Valid until
2024-05-26

Effective

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4160177	Certofix® Mono Paed S 110	III
4160177-01	Certofix® Mono Paed S 110	III
4160177-04	Certofix® Mono Paed S 110	III
4160185	Certofix® Mono S 215	III
4160185-07	Certofix® Mono S 215	III
4160185E	Certofix® Mono 215	III
4160185E-07	Certofix® Mono 215	III
4160207	Certofix® Mono S 220	III
4160207-07	Certofix® Mono S 220	III
4160207E	Certofix® Mono 220	III
4160207E-07	Certofix® Mono 220	III
4160207R	Certofix® Mono 220 R	III
4160215	Certofix® Mono V 220	III
4160215-07	Certofix® Mono V 220	III
4160223	Certofix® Mono S 315	III
4160223-07	Certofix® Mono S 315	III
4160223E	Certofix® Mono 315	III
4160223E-07	Certofix® Mono 315	III
4160231	Certofix® Mono V 315	III
4160231-07	Certofix® Mono V 315	III
4160258	Certofix® Mono S 320	III
4160258-07	Certofix® Mono S 320	III
4160258E	Certofix® Mono 320	III
4160258E-07	Certofix® Mono 320	III
4160258R	Certofix® Mono 320 R	III
4160258S	Certofix® Safety Mono S 320	III
4160258S-07	Certofix® Safety Mono S 320	III
4160266	Certofix® Mono V 320	III
4160266-07	Certofix® Mono V 320	III
4160266P	Certofix® protect Mono V 320	III
4160266P-07	Certofix® protect Mono V 320	III
4160282	Certofix® Mono S 330	III
4160282-07	Certofix® Mono S 330	III
4160282E	Certofix® Mono 330	III
4160282E-07	Certofix® Mono 330	III
4160282S	Certofix® Safety Mono S 330	III
4160282S-07	Certofix® Safety Mono S 330	III

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Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4160290	Certofix® Mono V 330	III
4160290-07	Certofix® Mono V 330	III
4160290P	Certofix® protect Mono V 330	III
4160290P-07	Certofix® protect Mono V 330	III
4160304	Certofix® Mono S 420	III
4160304-07	Certofix® Mono S 420	III
4160304E	Certofix® Mono 420	III
4160304E-07	Certofix® Mono 420	III
4160304R	Certofix® Mono 420 R	III
4160320	Certofix® Mono V 420	III
4160320-07	Certofix® Mono V 420	III
4160320P	Certofix® protect Mono V 420	III
4160320P-07	Certofix® protect Mono V 420	III
4160509	Certofix® Mono S 415	III
4160509-07	Certofix® Mono S 415	III
4160509E	Certofix® Mono 415	III
4160509E-07	Certofix® Mono 415	III
4160517	Certofix® Mono V 415	III
4160517-07	Certofix® Mono V 415	III
4160578	Certofix® Trio HF S 1215	III
4160578-07	Certofix® Trio HF S 1215	III
4160586	Certofix® Trio HF S 1220	III
4160586-07	Certofix® Trio HF S 1220	III
4160614	Certofix® Trio HF V 1215	III
4160614-07	Certofix® Trio HF V 1215	III
4160622	Certofix® Trio HF V 1220	III
4160622-07	Certofix® Trio HF V 1220	III
4160622P	Certofix® protect Trio HF V 1220	III
4160622P-07	Certofix® protect Trio HF V 1220	III
4160762	Certofix® Mono S 430	III
4160762-07	Certofix® Mono S 430	III
4160762E	Certofix® Mono 430	III
4160762E-07	Certofix® Mono 430	III
4160789	Certofix® Mono V 430	III
4160789-07	Certofix® Mono V 430	III
4160789P	Certofix® protect Mono V 430	III
4160789P-07	Certofix® protect Mono V 430	III
4161157E	Certofix® Trio 715	III
4161157E-07	Certofix® Trio 715	III

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4161159	Certofix® Trio S 715	III
4161159-07	Certofix® Trio S 715	III
4161211	Certofix® Duo V 720	III
4161211-07	Certofix® Duo V 720	III
4161211P	Certofix® protect Duo V 720	III
4161211P-07	Certofix® protect Duo V 720	III
4161319	Certofix® Duo V 730	III
4161319-07	Certofix® Duo V 730	III
4161319P	Certofix® protect Duo V 730	III
4161319P-07	Certofix® protect Duo V 730	III
4162153	Certofix® Trio V 715	III
4162153-07	Certofix® Trio V 715	III
4162153P	Certofix® protect Trio V 715	III
4162153P-07	Certofix® protect Trio V 715	III
4162200E	Certofix® Duo 720	III
4162200E-07	Certofix® Duo 720	III
4162307E	Certofix® Duo 730	III
4162307E-07	Certofix® Duo 730	III
4163206E	Certofix® Trio 720	III
4163206E-07	Certofix® Trio 720	III
4163214	Certofix® Trio V 720	III
4163214-07	Certofix® Trio V 720	III
4163214P	Certofix® protect Trio V 720	III
4163214P-07	Certofix® protect Trio V 720	III
4163303E	Certofix® Trio 730	III
4163303E-07	Certofix® Trio 730	III
4163306	Certofix® Trio S 730	III
4163306-07	Certofix® Trio S 730	III
4163306S	Certofix® Safety Trio S 730	III
4163306S-07	Certofix® Safety Trio S 730	III
4163311	Certofix® Trio V 730	III
4163311-07	Certofix® Trio V 730	III
4163311P	Certofix® protect Trio V 730	III
4163311P-07	Certofix® protect Trio V 730	III
4164156E	Certofix® Duo 715	III
4164156E-07	Certofix® Duo 715	III
4164158	Certofix® Duo S 715	III
4164158-07	Certofix® Duo S 715	III
4166159	Certofix® Duo V 715	III

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4166159-07	Certofix® Duo V 715	III
4166159P	Certofix® protect Duo V 715	III
4166159P-07	Certofix® protect Duo V 715	III
4166841	Certofix® Quinto V 1215	III
4166841-07	Certofix® Quinto V 1215	III
4166852	Certofix® Quinto S 1220	III
4166852-07	Certofix® Quinto S 1220	III
4166852S	Certofix® Safety Quinto S 1220	III
4166852S-07	Certofix® Safety Quinto S 1220	III
4166868	Certofix® Quinto V 1220	III
4166868-07	Certofix® Quinto V 1220	III
4166868P	Certofix® protect Quinto V 1220	III
4166868P-07	Certofix® protect Quinto V 1220	III
4166906	Certofix® Duo Paed S 408	III
4166906-07	Certofix® Duo Paed S 408	III
4166922	Certofix® Duo Paed S 413	III
4166922-07	Certofix® Duo Paed S 413	III
4166949	Certofix® Duo Paed S 420	III
4166949-07	Certofix® Duo Paed S 420	III
4167112	Certofix® Duo Paed S 508	III
4167112-07	Certofix® Duo Paed S 508	III
4167139	Certofix® Duo Paed S 513	III
4167139-07	Certofix® Duo Paed S 513	III
4167155	Certofix® Duo Paed S 520	III
4167155-07	Certofix® Duo Paed S 520	III
4167228	Certofix® Trio Paed S 508	III
4167228-07	Certofix® Trio Paed S 508	III
4167244	Certofix® Trio Paed S 513	III
4167244-07	Certofix® Trio Paed S 513	III
4167260	Certofix® Trio Paed S 520	III
4167260-07	Certofix® Trio Paed S 520	III
4167385	Certofix® Duo S 720	III
4167385-07	Certofix® Duo S 720	III
4167385S	Certofix® Safety Duo S 720	III
4167385S-07	Certofix® Safety Duo S 720	III
4167394	Certofix® Duo S 730	III
4167394-07	Certofix® Duo S 730	III
4167394S	Certofix® Safety Duo S 730	III
4167394S-07	Certofix® Safety Duo S 730	III

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Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4167408	Certofix® Trio S 720	III
4167408-07	Certofix® Trio S 720	III
4167408S	Certofix® Safety Trio S 720	III
4167408S-07	Certofix® Safety Trio S 720	III
4167511	Certofix® Duo HF V 920	III
4167511-07	Certofix® Duo HF V 920	III
4167538	Certofix® Duo HF V 1215	III
4167538-07	Certofix® Duo HF V 1215	III
4167546	Certofix® Duo HF V 1220	III
4167546-07	Certofix® Duo HF V 1220	III
4167767	Certofix® Quattro V 815	III
4167767-07	Certofix® Quattro V 815	III
4167767P	Certofix® protect Quattro V 815	III
4167767P-07	Certofix® protect Quattro V 815	III
4167775	Certofix® Quattro V 820	III
4167775-07	Certofix® Quattro V 820	III
4167775P	Certofix® protect Quattro V 820	III
4167775P-07	Certofix® protect Quattro V 820	III
4167775S	Certofix® Safety Quattro S 820	III
4167775S-07	Certofix® Safety Quattro S 820	III
4167783	Certofix® Quattro V 830	III
4167783-07	Certofix® Quattro V 830	III
4167783P	Certofix® protect Quattro V 830	III
4167783P-07	Certofix® protect Quattro V 830	III
4168518	Certofix® Duo HF V 715	III
4168518-07	Certofix® Duo HF V 715	III
4168528	Certofix® Duo HF S 720	III
4168528-07	Certofix® Duo HF S 720	III
4168534	Certofix® Duo HF V 720	III
4168534-07	Certofix® Duo HF V 720	III
4168534P	Certofix® protect Duo HF V 720	III
4168534P-07	Certofix® protect Duo HF V 720	III

Effective

Amendment Information

Version	Description of the changes
33	Delete "out of market" products 4160258N, 4160266N, 4160282N, 4160290N, 4160304N, 4160320N
32	Change product names from Certofix Mono S 220, Certofix Mono S 320, Certofix Mono S 420 to Certofix Mono 220 R, Certofix Mono 320 R, Certofix Mono 420 R of article numbers 4160207R, 4160258R, 4160304R due to corrections according to TÜV Süd, Certofix MDD extension (Order No. 713162581) Correction of product name Certofix Duo HF V 820 to Certofix Duo HF V 720 of article number 4168534
31	Change product name from Certofix Quattro S 820 to Certofix Quattro V 820 4167775, 4167775-07
30	Change of product name from Certofix Quattro V 820 and Certofix Safety Quattro V 820 to Certofix Quattro S 820 and Certofix Safety Quattro S 820 of article numbers 4167775, 4167775-07, 4167775S, 4167775S-07
29	Delete "out of market" products 4160193, 4160231IN, 4167503

Effective

Title: Declaration of Conformity - 39.05.106 - Certofix Initiator: Sandra ? Staufenberg

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Staufenberg, Sandra (stausade)
Title: Administrator Regulatory Affairs CoE Pain Control & CVC
Date: Monday, 25 May 2020, 11:38 W. Europe Daylight Time
Meaning: Document signed as Author
=====

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Monday, 25 May 2020, 14:02 W. Europe Daylight Time
Meaning: Approve Document
=====

UserName: Seidel, Stefan (seidstde)
Title: HC-RA-DE08E - Head of Regulatory Affairs CoE IV Systems
Date: Monday, 25 May 2020, 15:53 W. Europe Daylight Time
Meaning: Approve Document
=====

Effective

Declaration of Conformity

Manufacturer: PAKTEN SAĞLIK URUNLERI SANAYI VE TICARET A.S.

European Representative: N/A

Product Name: Bed Sheet, Adult Pants, Adult Diaper and Hygienic Baby Clenaning Towel

Model: Small, Medium, Large and Extra Large

Classification: Class I, Rule 1 (non- sterile) per Annex IX, 93/42 EEC Medical Devices Directive

Conformity Assessment Route:

- EN 14971:2001 STANDARD RISK ANALYSIS OF MEDICAL PRODUCTS
- EN 980:2003 (14368) MEDICAL DEVICE LABELING REQUIREMENTS

General Applicable Directive:

- EDNA Rewet
- EDNA Maximum Suction Hold

Standards Applied:

- EN 14971:2001 STANDARD RISK ANALYSIS OF MEDICAL PRODUCTS
- EN 980:2003 (14368) MEDICAL DEVICE LABELING REQUIREMENTS
- ISO 9001:2015 Quality Management Systems

Place, Date of Issue:

08.02.2021 / PAKTEN SAĞLIK URUNLERI SANAYI VE TICARET A.S.

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