

**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/ehereby declare in our own responsibility  
that the product/s**Certifix®****Certifix®****Certifix® Mono,  
Certifix® Mono Paed,  
Certifix® protect Mono,  
Certifix® Safety Mono****Certifix® Mono,  
Certifix® Mono Paed,  
Certifix® protect Mono,  
Certifix® Safety Mono****Certifix® Duo,  
Certifix® Duo HF,  
Certifix® Duo Paed,  
Certifix® protect Duo,  
Certifix® protect Duo HF,  
Certifix® Safety Duo****Certifix® Duo,  
Certifix® Duo HF,  
Certifix® Duo Paed,  
Certifix® protect Duo,  
Certifix® protect Duo HF,  
Certifix® Safety Duo****Certifix® Trio,  
Certifix® Trio HF,  
Certifix® Trio Paed,  
Certifix® protect Trio,  
Certifix® protect Trio HF,  
Certifix® Safety Trio****Certifix® Trio,  
Certifix® Trio HF,  
Certifix® Trio Paed,  
Certifix® protect Trio,  
Certifix® protect Trio HF,  
Certifix® Safety Trio****Certifix® Quattro,  
Certifix® protect Quattro,  
Certifix® Safety Quattro****Certifix® Quattro,  
Certifix® protect Quattro,  
Certifix® Safety Quattro****Certifix® Quinto,  
Certifix® protect Quinto,  
Certifix® Safety Quinto****Certifix® Quinto,  
Certifix® protect Quinto,  
Certifix® 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

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 14<sup>th</sup> 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

**Anlage I / Attachment I**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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

**Amendment Information**

<b>Version</b>	<b>Description of the changes</b>
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



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  
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