

Wir

We

**B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany**erklären in eigener Verantwortung,
dass das/die Produkt/e**Combitrans / Angiotrans**Monitoring-Sets zur invasiven Druckmessung
(Artikelnummern siehe Anlage)mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmenRichtlinie 93/42/EWG des Rates vom 14. Juni 1993
über Medizinprodukte
geändert durch Richtlinie 2007/47/EG**Konformitätsbewertungsverfahren**
nach Anhang II (ausgenommen Abschnitt 4)
der oben genannten Richtlinie**Klassifizierung**
gemäß Anhang IX der
oben genannten Richtlinie
Klasse IIa / Regel 2
Klasse IIb / Regel 10**Benannte Stelle**
TÜV SÜD Product Service GmbH (ID-Nr. 0123)
Ridlerstraße 65, 80339 München, Deutschland**Ausgestellte Bescheinigung(en):**
G1 012974 0608 Rev. 00**Datum der ersten CE-Kennzeichnung**
1996-10-16**Gültig bis**
2024-05-26hereby declare in our own responsibility
that the product/s**Combitrans / Angiotrans**Monitoring Sets for physiological pressure
measurement
(article numbers see attachment)

is/are in compliance with the following directive

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 (excluding section 4)
of the Council Directive named above**Classification**
according to annex IX of the
Council Directive named above
Class IIa / Rule 2
Class IIb / Rule 10**Notified Body**
TÜV SÜD Product Service GmbH (ID no. 0123)
Ridlerstraße 65, 80339 Munich, Germany**Certificate(s) issued:**
G1 012974 0608 Rev. 00**Date of first CE-marking**
1996-10-16**Valid until**
2024-05-26

Berlin, 2020-07-16

B. Braun Melsungen AG

i. A.

Dr. S. Vogelbein
Head of Quality Management CoE VS

Form: SA-DE03-M-5-1-12-000-4-D-DE/EN

Berlin, 2020-07-16

B. Braun Melsungen AG

i. V.

Dr. H. Schlicht
Head of Regulatory Affairs

Anlage I / Attachment ICombitrans Monitoring Sets
Combitrans Monitoring Kits

Art.-Nr. REF No.	Artikelbezeichnung	Article description	Klasse Class
5200011	Combitrans Double Monitoring Kit	Combitrans 2-fold Monitoring-Kit	IIb
5200181	Haemofix-Monitoring-Set, 2-fach, BEH	Haemofix-Monitoring-Kit double, BSS	IIb
5200182	Haemofix-Monitoring-Set, Arteriell, BEH	Haemofix-Monitoring-Kit arterial, BSS	IIb
5200183	Haemofix-Monitoring-Set, Arteriell/Venös, BEH	Haemofix-Monitoring-Kit arterial/venous, BSS	IIb
5200756	Combitrans Monitoring-Set 2-fach	Combitrans Monitoring-Set double	IIb
5200757	Exadyn Combitrans Monitoring-Set	Exadyn Combitrans Monitoring-Set	IIb
5200758	Combitrans Monitoring-Set arteriell	Combitrans Monitoring-Set arterial	IIb
5200759	Combitrans Monitoring-Set venös	Combitrans Monitoring-Set venous	IIb
5200830	Combitrans Monitoring-Set 2-fach	Combitrans Monitoring Set double	IIb
5200849	Combitrans Monitoring-Set 3-fach	Combitrans Monitoring Set triple	IIb
5201152	Combitrans Monitoring-Set 2-fach	Combitrans Monitoring Set 2-fold	IIb
5201152-1	Combitrans Monitoring-Set 2-fach	Combitrans Monitoring Kit 2-fold	IIb
5202507	Exadyn-Combitrans Monitoring-Set	Exadyn Combitrans Monitoring Kit	IIb
5202507-0	Exadyn-Combitrans Monitoring-Set	Exadyn-Combitrans Monitoring-Kit	IIb
5202604	Combitrans Monitoring-Set venös	Combitrans Monitoring Set venous	IIb
5202604-1	Combitrans Monitoring-Set venös	Combitrans Monitoring Kit venous	IIb
5202614	Combitrans-Monitoring Set venous long	Combitrans-Monitoring Set venous long	IIb
5202617	Combitrans Monitoring-Set pulmonal art.	Combitrans Monitoring Set pulmonary art.	IIb
5202620	Combitrans Monitoring-Set arteriell	Combitrans Arterial Monitoring Set	IIb
5202620-1	Combitrans Monitoring-Set arteriell	Combitrans Monitoring-Kit arterial	IIb
5203660	Combitrans 3 mit Adapter, lose Lockmutter	Combitrans transducer	IIb
5206994	Exadyn-Monitoring-Set (Lange Leitungen)	Exadyn Monitoring Set (long line)	IIb
5207167	Combitrans Monitoring Set Add-on	Combitrans Monitoring Set Add-on	IIb
5211247	Combitrans Monitoring-Set	Combitrans Monitoring-Set	IIb
5212391	Exadyn-Combitrans PVC-frei	Exadyn-Combitrans PVC-free	IIb
5213505	Haemofix-Combitrans Monitoring-Set art.	Haemofix-Combitrans Monitoring Set art.	IIb
5213516	Haemofix-Exadyn Monitoring-Set art. + ven.	Haemofix-Exadyn Monitoring Set art. + ven.	IIb
5213527	Haemofix-Combitrans Monitoring-Set 2-fach	Haemofix-Combitrans Monitoring Set double	IIb
5216200	Combitrans Monitoring-Set Klettband	Combitrans Monitoring Set Velcro	IIb

Combitrans Easy Click Monitoring Sets
 Combitrans Easy Click Monitoring Kits

Art.-Nr. REF No.	Artikelbezeichnung	Article description	Klasse Class
5311010	Combitrans EC Typ München Arteriell	Combitrans EC Type Munich Arterial	IIb
5311325	Combitrans EC Hämofix-Exadyn Set mit BEH	Combitrans EC Hämofix-Exadyn Set mit BEH	IIb
5312020	Combitrans EC Typ München Venös	Combitrans EC Type Munich Venous	IIb
5313030	Combitrans EC Typ Stuttgart	Combitrans EC Type Stuttgart	IIb
5318575	Combitrans EC Exadyn Set	Combitrans EC Exadyn Kit	IIb
5318762	Combitrans-EC-Set 2-fach	Combitrans EC Set 2-fold	IIb
5318764	COMBITRANS-EC-Set 1-fach	COMBITRANS-EC-Set 1-fold	IIb
5318766	Combitrans-EC-Set 3 ½-fach	Combitrans-EC-Set 3 ½-fold	IIb
5318767	COMBITRANS-EC-Set 2-fach	COMBITRANS EC kit 2-fold	IIb
5318768	Combitrans-EC, 3-fach	Combitrans-EC, 3-fold	IIb
5318771	Combitrans-EC-Set 2-fach plus	Combitrans EC kit double plus	IIb
5318776	Combitrans EC Monitoring Set ADD ON	Combitrans EC Monitoring Kit ADD ON	IIb
5319289	Combitrans EC Arteriell	Combitrans EC Arterial	IIb
5319290	Combitrans EC Venös	Combitrans EC Venous	IIb
5319295	CEC Haemofix Set Arteriell BEH	CEC Haemofix Kit Arterial CBSS	IIb
5319300	CEC Haemofix-Exadyn Set	CEC Haemofix-Exadyn Kit	IIb
5319305	CEC Haemofix Monitoring-Set 2-fach	CEC Haemofix Monitoring-Kit, Double	IIb
5319771	Combitrans EC, 3-fach plus	Combitrans EC, 3-fold plus	IIb

Angiotrans
 Angiotrans

Art.-Nr. REF No.	Artikelbezeichnung	Article description	Klasse Class
5019505	Angiotrans 2-Fach, OFF Mitteldruck, RR	Anigotrans 2-Port, OFF Mid Pressure, RR	IIb

Combitrans Zubehör
 Combitrans Accessories

Art.-Nr. REF No.	Artikelbezeichnung	Article description	Klasse Class
5200359	Add-On mit BEH	Add-On with BEH	IIa

Title: Combitrans_Angiotrans_39.05.616_DOC Initiator: Annesha ? Lahiri

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

UserName: Lahiri, Annesha (lahiande)
Title: Regulatory Affairs Manager
Date: Wednesday, 12 May 2021, 17:51 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Schlicht, Henning (schlhgde)
Title: Head of Regulatory Affairs
Date: Friday, 14 May 2021, 14:54 W. Europe Daylight Time
Meaning: Approve Document
