

Arteriofix

Arterial catheter kits



Arteriofix

Arterial catheter kit for invasive monitoring of blood pressure and blood sampling using the Seldinger technique

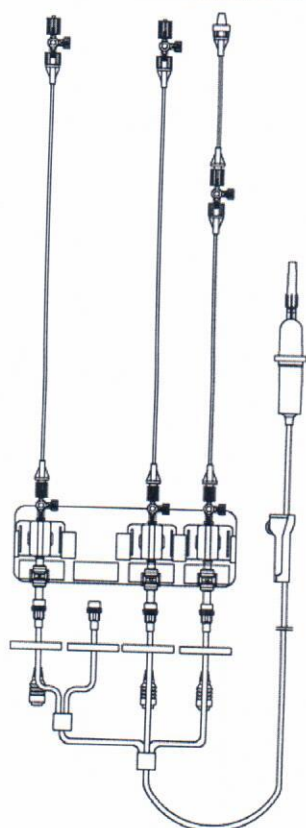
- **Introducer needle** made of stainless steel
 - smoothly tapered hub transition for easy insertion of guide wire
 - integrated design, providing smooth transition from guide wire to needle and needle to catheter to ensure minimal trauma at puncture site
 - Luer lock fitting
- **Catheter** made of FEP
 - for pressure transmission and good physical and mechanical properties of the material
 - excellent tissue and blood compatibility
 - smooth surface prevents thrombogenesis
 - special tip for easy insertion
 - FEP catheters have good gliding characteristics during insertion
 - fixation wings at proximal end
 - colour-coded Luer lock-fittings
- **Guide wire** made of stainless steel
 - flexible straight tip
 - designed according to the different inner diameters of catheters

colour	size	capillary: mm [Ø]; length [mm]	needle: Ø [G; mm]; length [mm]	wire: length [cm] - Ø [Inch]	Code- Number	Sales unit-pcs.
Arteriofix Catheter kits						
yellow	22G/ 80 mm	0.87; 80	22; 0.80 x 50	25-0.021	5206316	20
red	20G/ 80 mm	1.08; 80	20; 0.95 x 50	25-0.025	5206324	20
white	20G/160 mm	1.08; 160	20; 0.95 x 70	40-0.025	5206332	20
grey	18G/160 mm	1.29; 160	18; 1.30 x 70	40-0.035	5206359	20



Combitrans Special

Monitoring kits with disposable transducer Customized kit solutions



Combitrans Monitoring Double Kit (without illustration)

- Intrafix special administration kit, double
- two Combitrans disposable transducers with flush device 3 ml/h and Discofix three-way stopcock (red and blue)
- two Combidyn pressure tubing 125 cm (red and blue)
- two Discofix three-way stopcocks (red and blue)
- Combidyn 20 cm red as arterial extension

Combitrans Monitoring Double Kit (without illustration)

without attachment plate

5201152

20

with attachment plate

5200830

20

Combitrans Monitoring Triple Kit (without illustration)

Same as Combitrans monitoring double kit but with

- Intrafix special administration kit, triple
- additional Combitrans disposable transducer with flush system and Discofix three-way stopcock yellow
- Combidyn pressure tubing 125 cm yellow connected with Discofix three-way stopcock yellow
- mounted on a quadruple plate

Combitrans Monitoring triple kit (without illustration)

5200849

20





Product Service

EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)
(Devices in Class IIa, IIb or III)

No. G1 15 04 12974 422

Manufacturer:**B. Braun Melsungen AG**

Carl-Braun-Str. 1
34212 Melsungen
GERMANY

Facility(ies):

B. Braun Melsungen AG Vascular Systems
Mistelweg 2, 12357 Berlin, GERMANY

AESCLAP CHIFA Sp. z o.o.
ul. Tysiaclecia 14, 64-300 Nowy Tomysl, POLAND

B. Braun Melsungen AG Vascular Systems
Sieversufer 8, 12359 Berlin, GERMANY

Product**Category(ies):**

Coronary stent systems, PTCA catheters, PTA catheters,
PTCA guide wires and sets,
Probes for stimulation and electrophysiology,
Procedure Kits,
Angiography sets, manifolds, guide wires,
single use Right heart pulmonary artery catheters,
Monitoring sets for invasive physiological
pressure measurement,
Introducer sheaths and sets,
Arterial puncture cannulae, arterial catheter sets

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

Report No.:

713055006

Valid from:

2015-06-16

Valid until:

2020-06-13

Hans-Heiner Junker

Date, 2015-06-18

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

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**Konformitätserklärung
Declaration of Conformity**

Document-No.: 39.05.641

Revision-No.: 14

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Page: 1 of 2

Wir

We

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

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

Arteriofix

Arterienpunktionskanülen, Arterien-Katheter-Set
(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen

Richtlinie 93/42/EWG des Rates vom 14. Juni 1993
über Medizinprodukte

Konformitätsbewertungsverfahren
nach Anhang II (ausgenommen Abschnitt 4)
der oben genannten Richtlinie

Klassifizierung
gemäß Anhang IX der
oben genannten Richtlinie
Klasse IIa / Regel 7

Benannte Stelle
TÜV SÜD Product Service GmbH (ID-Nr. 0123)
Ridlerstraße 65, 80339 München, Deutschland

Datum der ersten CE-Kennzeichnung
1996-06-13

Gültig bis
2020-06-13

Berlin, 2015-06-19

B. Braun Melsungen AG

i. A.



R. Lorenz
Head of Quality Management

hereby declare in our own responsibility
that the product/s

Arteriofix

Arterial puncture needle, Arterial Catheter Set
(article numbers see attachment I)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14th June 1993
concerning Medical Devices

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 7

Notified Body
TÜV SÜD Product Service GmbH (ID-No. 0123)
Ridlerstraße 65, 80339 Munich, Germany

Date of first CE-marking
1996-06-13

Valid until
2020-06-13

Berlin, 2015-06-19

B. Braun Melsungen AG

i. V.


Dr. B. Jänicke
Head of Regulatory Affairs Management



**Konformitätserklärung
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Effective Date: 2015-06-19

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Anlage I / Attachment I

Art.-Nr. / Art. No.	Artikelbezeichnung	Article description	Klasse / Class
5206316	Arteriofix Art.-Kath.-Set 22G/80 mm	Arteriofix 22G/80 mm	IIa
5206324	Arteriofix Art.-Kath.-Set 20G/80 mm	Arteriofix 20G/80 mm	IIa
5206332	Arteriofix Art.-Kath.-Set 20G/160 mm	Arteriofix 20G/160 mm	IIa
5206359	Arteriofix Art.-Kath.-Set 18G/160 mm	Arteriofix 18G/160 mm	IIa
5206345	Arteriofix Art.-Kath.-Set 18G/80 mm	Arteriofix 18G/80 mm	IIa



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Declaration of Conformity

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Wir

We

B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germanyerklären in eigener Verantwortung,
dass das/die Produkt/e**Combidyn / Combitrans / Angiotrans**

Monitoring-Sets zur invasiven Druckmessung

(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmenRichtlinie 93/42/EWG des Rates vom 14. Juni 1993
über Medizinprodukte**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**Datum der ersten CE-Kennzeichnung**
1996-10-16**Gültig bis**
2015-06-13

Berlin, 2014-10-10

B. Braun Melsungen AG

i. A.


R. Lorenz
Head of Quality Managementhereby declare in our own responsibility
that the product/s**Combidyn / Combitrans / Angiotrans**Monitoring Sets for physiological pressure
measurement

(article numbers see attachment I)

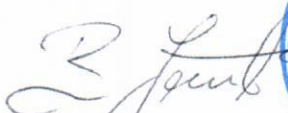
is/are in compliance with the following directive

Council Directive 93/42/EEC of 14th June 1993
concerning Medical Devices**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**Date of first CE-marking**
1996-10-16**Valid until**
2015-06-13

Berlin, 2014-10-10

B. Braun Melsungen AG

i. V.


Dr. B. Jänicke
Head of Regulatory Affairs Management

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Anlage I / Attachment I

Art.-Nr. / Art. No.	Artikelbezeichnung	Article description	Klasse / Class
5205689	Combidyn Monitoring Set ohne Druckdome	Combidyn Monitoring Set w/o Pressure Dome	IIa
5206502	Combidyn Monitoring Set P23ID	Combidyn Monitoring Set for Gould P23ID	IIa
5207410	Combidyn Monitoring Set SensoNor 840	Combidyn Monitoring Set SensoNor 840	IIa
5207070	Combidyn Monitoring Set HP 1295C	Combidyn Monitoring Set HP 1295C	IIa
5201500	Combidyn Spülsystem 3ml/Std.	Combidyn flush device 3 ml/h	IIa
5904001	SensoNor 844 Druckumwandler	SensoNor 844 Transducer	IIa
5204917	Combidyn Druckdom Gould Statham P23-ID	Combidyn Dome Statham Gould P23ID	IIa
844-31	Druckdom SensoNor 844 mt DWH	Druckdom SensoNor 844 mit DWH	IIa
5203320	SensoNor Druckdom DWH Rot ZWH weiss	SensoNor 844 pressure dome red/white stopcock	IIa
5204100	Combidyn Druckdom AE 840-23	Combidyn pressure dome AE 840-23	IIa
5207231	Combidyn disposable domes HP	Combidyn disposable domes HP	IIa
5204984	Combidyn Druckschlauch trans 20 cm PVC	Combidyn PVC press. tubing transp. 20 cm	IIa
5204992	Combidyn Druckschlauch trans 30 cm PVC	Combidyn PVC press. tubing transp. 30 cm	IIa
5205000	Combidyn Druckschlauch trans 50 cm PVC	Combidyn PVC press. tubing transp. 50 cm	IIa
5205018	Combidyn Druckschlauch trans 100 cm PVC	Combidyn PVC press. tubing transp. 100 cm	IIa
5211280	Combidyn Druckschlauch trans 125 cm PVC	Combidyn PVC press. tubing transp. L125 cm	IIa
5205026	Combidyn Druckschlauch trans 150 cm PVC	Combidyn PVC press. tubing transp. 150 cm	IIa
5205034	Combidyn Druckschlauch trans 200 cm PVC	Combidyn PVC press. tubing transp. 200 cm	IIa
5204941	Combidyn Druckschlauch rot 20 cm PVC	Combidyn PVC pressure tubing red 20 cm	IIa
5204976	Combidyn Druckschlauch rot 100 cm PVC	Combidyn PVC pressure tubing red 100 cm	IIa
5205042	Combidyn Druckschlauch rot 150 cm PVC	Combidyn PVC pressure tubing red 150 cm	IIa
5205050	Combidyn Druckschlauch rot 200 cm PVC	Combidyn PVC press. tubing red 200 cm	IIa
5205255	Combidyn Druckschlauch blau 100 cm PVC	Combidyn PVC press. tubing blue 100 cm	IIa
5205263	Combidyn Druckschlauch blau 150 cm PVC	Combidyn pressure tubing blue 150 cm	IIa



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5205271	Combidyn Druckschlauch blau 200 cm PVC	Combidyn pressure tubing blue 200 cm	Ila
5208000	Combidyn-PVC-Ltg. 1,5 x 2,7 x 200 mm, transp.	Combidyn press. line 200 mm, transp.	Ila
5208020	Combidyn-PVC-Ltg. 1,5 x 2,7 x 300 mm, transp.	Combidyn press. line 1.5 x 2.7 x 300 mm transp	Ila
5208080	Combidyn-PVC-Ltg. 1,5 x 2,7 x 750 mm, transp.	Combidyn press. line 750 mm, transp.	Ila
5208090	Combidyn-PVC-Ltg. 1,5 x 2,7 x 1000 mm, transp.	Combidyn press. line 1000 mm, transp.	Ila
5208599	Combidyn Druckschl. mit DWH rot/20 cm PVC	Combidyn PVC tube with stopcock red 20 cm	Ila
5201345	Combidyn-Druckschlauch PE 60 cm, 1 x 2, tr	Combidyn-press. tube PE 60 cm, transp.	Ila
5204995	Combidyn-Druckschlauch 1 x 2 x 150 mm transp.	Combidyn-press. tube PE 15 cm, transp.	Ila
5214993	Combidyn-Druckschlauch PE 30 cm 1 x 2, tr	Combidyn-press. tube PE 30 cm, transp.	Ila
5215019	Combidyn-Druckschlauch PE 100 cm 1 x 2, tr	Combidyn-press. tube PE 100 cm, transp.	Ila
5201281	Combidyn-Druckschlauch PE 120 cm, transp	Combidyn-press. tube PE 120 cm, transp.	Ila
5215027	Combidyn-Druckschlauch PE 150 cm, transp	Combidyn-press. tube PE 150 cm, transp.	Ila
5201337	Combidyn-Druckschlauch PE 180 cm, transp	Combidyn-press. tube PE 180 cm, transp.	Ila
5215035	Combidyn-Druckschlauch PE 200 cm, transp	Combidyn-press. tube PE 200 cm, transp	Ila
5201272	Combidyn-Druckschlauch PE 240 cm, transp	Combidyn-press. tube PE 240 cm, transp.	Ila
5204950	Combidyn-Druckschlauch 30 cm 1,0 x 2,0, rot	Combidyn-press. tube PE 30 cm, red	Ila
5215043	Combidyn Druckschlauch PE 150 cm, 1 x2 rot	Combidyn-press. tube PE 150 cm, red	Ila
5205239	Combidyn-Druckschlauch 30 cm 1,0 x 2,0, blau	Combidyn-press. tube PE 30 cm, blue	Ila
5215264	Combidyn-Druckschlauch PE 150 cm, 1 x 2 blau	Combidyn-press. tube PE 150 cm, blue	Ila
5210577	Combidyn Druckschlauch 150 cm blau m/m	Combidyn press. tube 150 cm blue m/m	Ila
5206634	Combifix Adapter weiblich/weiblich	Combifix Adapter female/female	Ila
5206642	Combifix Adapter männlich/männlich	Combifix Adapter male/male	Ila
5202620	Combitrans Monitoring-Set arteriell	Combitrans Arterial Monitoring Set	Ilb
5202604	Combitrans Monitoring-Set venös	Combitrans Monitoring Set venous	Ilb
5202617	Combitrans Monitoring-Set pulmonal art.	Combitrans Monitoring Set pulmonary art.	Ilb



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5202507	Exadyn-Combitrans Monitoring-Set	Exadyn Combitrans Monitoring Set	IIb
5212391	Exadyn-Combitrans PVC-frei	Exadyn-Combitrans PVC-free	IIb
5206994	Exadyn-Monitoring-Set (Lange Leitungen)	Exadyn Monitoring Set (long line)	IIb
5213330	Exadyn-Monitoring-Set Paediatric	Exadyn-Monitoring-Kit Pediatrics	IIb
5216200	Combitrans Monitoring-Set Klettband	Combitrans Monitoring Set Velcro	IIb
5075060	Combitrans-Monitoring-Set	Combitrans Monitoring Set	IIb
5200490	Combitrans-Monitoring-Set	Combitrans Monitoring Set	IIb
5201152	Combitrans Monitoring-Set 2-fach	Combitrans Monitoring Set 2-fold	IIb
5211110	Combitrans- Set arteriell, Paediatric	Combitrans-Kit arterial, Pediatrics	IIb
5211247	Combitrans Monitoring-Set	Combitrans Monitoring-Set	IIb
5212220	Combitrans- Set venös, Paediatric	Combitrans-Kit venous, Pediatrics	IIb
5200830	Combitrans Monitoring-Set 2-fach	Combitrans Monitoring Set double	IIb
5200849	Combitrans Monitoring-Set 3-fach	Combitrans Monitoring Set triple	IIb
5207167	Combitrans Monitoring Set Add-on	Combitrans Monitoring Set Add-on	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
5211700	Combitrans Monitoring-Set, PVC-frei	Combitrans Monitoring-Set, PVC-free	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
5200310	Add-On-Set Haemofix	Add-On-Kit Haemofix	IIa
5200359	Add-On mit BEH	Add-On with BEH	IIa
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
5203660	Combitrans 3 mit Adapter, lose Lockmutter	Combitrans transducer	IIb
40700380	Intrafix 180 cm, unbelüftet	Intrafix 180 cm, non-ventilated	IIa
5200411	Blutentnahmehahn	Stopcock for blood sampling	IIa
5213940	Entnahmeadapter BES	Sampling adapter Luer Lock	IIa



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5310000	Platzhalter Combitrans EC	Dummy Combitrans EC	I Ib
5311010	Combitrans EC Typ München Arteriell	Combitrans EC Type Munich Arterial	I Ib
5312020	Combitrans EC Typ München Venös	Combitrans EC Type Munich Venous	I Ib
5313030	Combitrans EC Typ Stuttgart	Combitrans EC Type Stuttgart	I Ib
5318575	Combitrans EC Exadyn Set	Combitrans EC Exadyn Kit	I Ib
5318762	Combitrans-EC-Set 2-fach	Combitrans EC Set 2-fold	I Ib
5318766	Combitrans-EC-Set 3 ½-fach	Combitrans-EC-Set 3 ½-fold	I Ib
5318768	Combitrans-EC, 3-fach	Combitrans-EC, 3-fold	I Ib
5318776	Combitrans EC Monitoring Set ADD ON	Combitrans EC Monitoring Kitt ADD ON	I Ib
5319289	Combitrans EC Arteriell	Combitrans EC Arterial	I Ib
5319290	Combitrans EC Venös	Combitrans EC Venous	I Ib
5319295	CEC Haemofix Set Arteriell BEH	CEC Haemofix Kit Arterial CBSS	I Ib
5319300	CEC Haemofix-Exadyn Set	CEC Haemofix-Exadyn Kit	I Ib
5319305	CEC Haemofix Monitoring-Set 2-fach	CEC Haemofix Monitoring-Kit, Double	I Ib
5330849	Combitrans Set 3-fach PVC-frei	Combitrans Kit Triple PVC-free	I Ib
5331152	Combitrans Set 2-fach PVC-frei	Combitrans Kit Double PVC-free	I Ib
5332604	Combitrans Set venös PVC-frei	Combitrans Kit venous PVC-free	I Ib
5332617	Combitrans Set PA PVC-frei	Combitrans Kit PA PVC-free	I Ib
5332620	Combitrans Set arteriell PVC-frei	Combitrans Kit arterial PVC-free	I Ib
5019505	Angiotrans 2-Fach, OFF Mitteldruck, RR	Anigotrans 2-Port, OFF Mid Pressure, RR	I Ib

