

Wir

We

**B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany**erklären in eigener Verantwortung,
dass das/die Produkt/e**Combidyn**Druckschläuche
(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**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**Combidyn**Pressure Tubings
(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**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, 2020-05-19

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, 2020-05-19

B. Braun Melsungen AG

i. V.

Dr. H. Schlicht
Head of Regulatory Affairs

Effective

Anlage I / Attachment I

Art.-Nr. REF No.	Artikelbezeichnung	Article description	Klasse Class
5201281	Combidyn-Druckschlauch PE 120 cm, transp	Combidyn-press. tube PE 120 cm, transp.	IIa
5201337	Combidyn-Druckschlauch PE 180 cm, transp	Combidyn-press. tube PE 180 cm, transp.	IIa
5201345	Combidyn-Druckschlauch PE 60 cm, 1 x 2, tr	Combidyn-press. tube PE 60 cm, transp.	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
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
5204995	Combidyn-Druckschlauch 1 x 2 x 150 mm transp.	Combidyn-press. tube PE 15 cm, transp.	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
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
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
5205271	Combidyn Druckschlauch blau 200 cm PVC	Combidyn pressure tubing blue 200 cm	IIa
5208000	Combidyn-PVC-Ltg. 1,5 x 2,7 x 200 mm, transp.	Combidyn press. line 200 mm, transp.	IIa
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	IIa
5208080	Combidyn-PVC-Ltg. 1,5 x 2,7 x 750 mm, transp.	Combidyn press. line 750 mm, transp.	IIa
5208090	Combidyn-PVC-Ltg. 1,5 x 2,7 x 1000 mm, transp.	Combidyn press. line 1000 mm, transp.	IIa
5208599	Combidyn Druckschl. mit DWH rot/20 cm PVC	Combidyn PVC tube with stopcock red 20 cm	IIa

5211280	Combidyn Druckschlauch trans 125 cm PVC	Combidyn PVC press. tubing transp. L125 cm	IIa
5214993	Combidyn-Druckschlauch PE 30 cm 1 x 2, tr	Combidyn-press. tube PE 30 cm, transp.	IIa
5215019	Combidyn-Druckschlauch PE 100 cm 1 x 2, tr	Combidyn-press. tube PE 100 cm, transp.	IIa
5218598	Combidyn Druckschl. mit DWH rot 15 cm PE	Combidyn press. tube w. 3-way sto red 15	IIa
5215027	Combidyn-Druckschlauch PE 150 cm, transp	Combidyn-press. tube PE 150 cm, transp.	IIa
5215035	Combidyn-Druckschlauch PE 200 cm, transp	Combidyn-press. tube PE 200 cm, transp	IIa
5201272	Combidyn-Druckschlauch PE 240 cm, transp	Combidyn-press. tube PE 240 cm, transp.	IIa
5204950	Combidyn-Druckschlauch 30 cm 1,0 x 2,0, rot	Combidyn-press. tube PE 30 cm, red	IIa
5215043	Combidyn Druckschlauch PE 150 cm, 1 x2 rot	Combidyn-press. tube PE 150 cm, red	IIa
5205239	Combidyn-Druckschlauch 30 cm 1,0 x 2,0, blau	Combidyn-press. tube PE 30 cm, blue	IIa
5215264	Combidyn-Druckschlauch PE 150 cm, 1 x 2 blau	Combidyn-press. tube PE 150 cm, blue	IIa
5210577	Combidyn Druckschlauch 150 cm blau m/m	Combidyn press. tube 150 cm blue m/m	IIa

Title: Combidyn Tubes_39.05.619_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, 17:50 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Schlicht, Henning (schlhgde)
Title: Head of Regulatory Affairs
Date: Friday, 14 May 2021, 14:53 W. Europe Daylight Time
Meaning: Approve Document
