

Wir

We

B. Braun Avitum AG
Schwarzenberger Weg 73-79
34212 Melsungen
Germany

erklären in eigener Verantwortung,
dass das/die Produkt/e
**Lines for Dialysis
and Hemo(dia)filtration**
(Artikelnummern siehe Anlage I)

hereby declare in our own responsibility
that the product/s
**Lines for Dialysis
and Hemo(dia)filtration**
(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

Council Directive 93/42/EEC of 14 June 1993
concerning medical devices

Konformitätsbewertungsverfahren:
nach Anhang II mit Ausnahme der nummer (4)
der oben genannten Richtlinie
Klassifizierung
gemäß Anhang IX der oben genannten Richtlinie:
Klasse IIa regel 2
EG-Zertifikat Nr.
G1 066097 0096 Rev. 02

Conformity assessment procedure:
according to annex II excluding (4)
of the Directive named above
Classification
according to annex IX of the Directive named above:
Class IIa, Rule 2
EC Certificate No.
G1 066097 0096 Rev. 02

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

Notified body:
TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 Munich, Germany
Identification number 0123

Datum der ersten CE-Kennzeichnung:
1998-02

Date of first CE-marking:
1998-02


Doc #: 29/15-RA-cb
Doc Rev #: 21.0
Rev date: 2020-11-20

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Gültigkeit dieser Erklärung:
von 2020-11-25
bis 2024-05-26

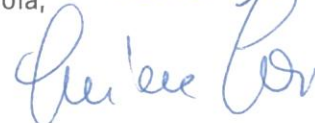
Validity of this declaration:
from 2020-11-25
until 2024-05-26

Radeberg, 2020-11-23



Anton Deisser
Head of CoE Fluids, Concentrates and Disposables

Mirandola, 2020-11-20



Dr. Giuliana Gavioli
Head of Division RA

Anlage I / Attachment I

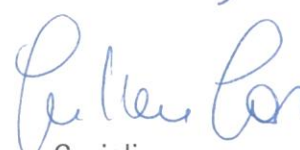
Art. No.	Description	Class	Rule	Accessory
PP001869	SOLU-CARE "T" Infusion Set / Set Infusione a "T"	Ila	2	X
721055A	HDF on-line tubing	Ila	2	X
7020250	Substitution line for Dialog	Ila	2	X
7036604	A/V set for Dialog	Ila	2	
7039533	A/V set for Miroclav	Ila	2	
7210224	Transducer protector	Ila	2	X
7210558	HDF on-line tubing	Ila	2	X
7210559	Adapter for predilution	Ila	2	X
7210588	A/V set for Dialog	Ila	2	
7210611	A/V SN / CO Set for Dialog	Ila	2	
7210645	A/V set SN for Dialog	Ila	2	
7210670	Transducer protector	Ila	2	X
7210684	A/V set for Dialog	Ila	2	
7210697	A/V set for Dialog	Ila	2	
7210698	A/V SN / CO Set for Dialog	Ila	2	
7210713	A/V set for Dialog	Ila	2	
7210728	Extension line mm 200	Ila	2	X
7210729	Extension line mm 400	Ila	2	X
7210785	A/V set for Dialog	Ila	2	
7210833	Recirculation connector	Ila	2	X
7210834	Substitution line for Dialog	Ila	2	X
7210868	Y Single needle adapter	Ila	2	X
7210892	A/V Set for Dialog, Gambro, Althin, Fresenius	Ila	2	
7210894	Arterial line for Dialog	Ila	2	
7210895	Venous line for Dialog	Ila	2	
7210896	Arterial line for Nipro	Ila	2	
7210897	Arterial line for Fresenius, Gambro, Althin	Ila	2	
7210898	Venous line for FMC, Gambro, Althin, Nipro	Ila	2	
721061200	A/V Set for Gambro AK 100-200	Ila	2	
721061210	A/V Set for FMC 2008-4008	Ila	2	
721061230	A/V Set SN for Gambro AK 100-200	Ila	2	
721061240	A/V Set for FMC 2008-4008	Ila	2	
721061250	A/V HDF Set for Gambro AK 100-200	Ila	2	
721061260	A/V Set for Nikkiso DBB 03-05-07	Ila	2	
721061270	A/V Set SN for Nikkiso DBB 03-05-07	Ila	2	
7210971	Blood restitution adapter	Ila	2	
7211031	A/V Set DEHP-Free PVC for Dialog with Infusion Set	Ila	2	
7211032	A/V SN/CO Set DEHP-Free PVC for Dialog	Ila	2	

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7211033	A/V Set DEHP-Free PVC For Dialog	Ila	2	
7211034	A/V Set DEHP-Free PVC For Dialog with HDF on-Line	Ila	2	
7211035	A/V Set DEHP-Free PVC for Dialog	Ila	2	
7211041	A/V Set for Dialog	Ila	2	
7211044	A/V Set DEHP-Free PVC for Dialog with Infusion Set	Ila	2	
7211062	Low Volume A/V SET DEHP-FREE PVC for Dialog	Ila	2	
7211104	A/V Set for Gambro	Ila	2	
7211105	Reinfusion Set with non-return Valve	Ila	2	X
7211115	HDF ON LINE TUBING KIT	Ila	2	X
7211116	ADAPTER FOR PREDILUTION	Ila	2	X
7211117	Y SINGLE NEEDLE ADAPTER	Ila	2	X
7211118	SN CO A/V Set DEHP-Free PVC for Dialog W/Inf. Set	Ila	2	
7211121	AV Set for Dialog with recirculation system for ECOPRIME concept	Ila	2	
7211122	Recirculation Kit	Ila	2	X
7211124	DiaStream® iQ Standard A/V System for Dialog iQ	Ila	2	
7211125	DiaStream® iQ High Performance A/V System for Dialog iQ	Ila	2	
7211126	DiaStream® iQ SN CO A/V System for Dialog iQ	Ila	2	
7211127	DiaStream® iQ SN CO A/V System with POD for Dialog iQ	Ila	2	
7211128	DiaStream® iQ HDF Combi System for Dialog iQ	Ila	2	
7211130	DiaStream® iQ HDF Line for Dialog iQ	Ila	2	
7211131	SN CO Set for Dialog with Recirculation System for ECOPRIME concept	Ila	2	
7211132	Set for Dialog with Recirculation System and IV Line for ECOPRIME concept	Ila	2	
7211140	T Infusion Set	Ila	2	X
7211141	A/V Set for Gambro AK 100-200	Ila	2	
7211142	A/V Set for Dialog, Gambro, Fresenius	Ila	2	
7211143	A/V Set for Dialog	Ila	2	
7211144	A/V Set for Dialog	Ila	2	
7211161	GAMBRO Set AK 100-200 with recirculation system	Ila	2	
7211162	FMC Set 2008-4008 with recirculation system	Ila	2	
7211163	GAMBRO SN Set AK 100-200 with recirculation system	Ila	2	
7211164	FMC SN Set 2008-4008 with recirculation system	Ila	2	
7211165	NIKKISO Set DBB 03-05-07 with recirculation system	Ila	2	
7211166	NIKKISO SN Set DBB 03-05-07 with recirculation system	Ila	2	
7211168	DIALOG, FMC, GAMBRO AK Set with recirculation system	Ila	2	
7211169	GAMBRO HDF Set AK 100-200 with recirculation system	Ila	2	
7211175	A/V Set for FMC 2008-4008	Ila	2	
7211182	Set DEHP-Free PVC for Dialog with recirculation system ECOPRIME	Ila	2	
7211183	DiaStream® iQ High Performance HDF Combi System for Dialog iQ	Ila	2	
7211195	A/V Set for Dialog, FMC, Gambro AK, Nipro	Ila	2	
7211200	DiaStream® A/V Bloodlines for Dialog, AK 100/200, FMC 2008/4008	Ila	2	

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7211201	DiaStream® A/V Bloodlines for Dialog, AK 100/200, FMC 2008/4008	Ila	2	
7211202	DiaStream® A/V Bloodlines for Dialog, AK 100/200, FMC 2008/4008	Ila	2	
7211203	DiaStream® A/V Bloodlines for Dialog, AK 100/200, FMC 2008/4008	Ila	2	
7211204	DiaStream® A/V Bloodlines for Dialog, AK 100/200, FMC 2008/4008	Ila	2	
7211205	DiaStream® A/V Bloodlines for Dialog	Ila	2	
7211206	DiaStream® A/V Bloodlines for Dialog	Ila	2	
7211207	DiaStream® A/V Bloodlines for Dialog	Ila	2	
7211208	DiaStream® A/V Bloodlines for Dialog	Ila	2	
7211213	A/V Set for Dialog DEHP-Free PVC Needle Free	Ila	2	
7211307	DiaStream® A/V Bloodlines for Dialog, AK 100/200, FMC 2008/4008	Ila	2	
7211308	DiaStream® A/V Bloodlines for Dialog, AK 100/200, FMC 2008/4008	Ila	2	
7211309	DiaStream® A/V Bloodlines for Dialog, AK 100/200, FMC 2008/4008	Ila	2	
7211310	DiaStream® A/V Bloodlines for Dialog, AK 100/200, FMC 2008/4008	Ila	2	
7211311	DiaStream® A/V Bloodlines for Dialog, AK 100/200, FMC 2008/4008	Ila	2	
7211312	DiaStream® A/V Bloodlines for Dialog	Ila	2	
7211313	DiaStream® A/V Bloodlines for Dialog	Ila	2	
7211314	DiaStream® A/V Bloodlines for Dialog	Ila	2	
7211315	DiaStream® A/V Bloodlines for Dialog	Ila	2	
7211365	A/V Set for Dialog with bag and recirculation connector	Ila	2	
7211366	A/V Set for Dialog	Ila	2	
7211408	A/V Set for Dialog	Ila	2	
7211409	A/V Set for Dialog	Ila	2	
7211410	A/V Set for Dialog, Gambro, Althin, Fresenius	Ila	2	
7211411	A/V Set for FMC 2008-4008	Ila	2	
7211412	Reinfusion adapter	Ila	2	X
7211472	DiaStream® iQ Standard A/V System for Dialog iQ	Ila	2	
7211473	DiaStream® iQ High Performance A/V System for Dialog iQ	Ila	2	
7211474	DiaStream® iQ SN CO A/V System for Dialog iQ	Ila	2	
7211475	DiaStream® iQ SN CO A/V System with POD for Dialog iQ	Ila	2	
7211476	DiaStream® iQ HDF Combi System for Dialog iQ	Ila	2	
7211477	DiaStream® iQ HDF Line for Dialog iQ	Ila	2	X
7211478	DiaStream® iQ Standard A/V System for Dialog iQ	Ila	2	
7211528	DiaStream® AV Bloodline Systems for Hemodialysis for Dialog, FMC 2008/4008, Gambro AK 95/96/98/100/200	Ila	2	

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