

Wir

We

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

erklären in eigener Verantwortung,
dass das/die Produkt/e
DiaStream®
(Artikelnummern siehe Anlage I)

hereby declare in our own responsibility
that the product/s
DiaStream®
(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:
2019-12

Date of first CE-marking:
2019-12

Doc #: 28/20-RA-mp
Doc Rev #: 3.0
Rev date: 2021-04-26

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Doc Rev #: 3.0
Rev date: 2021-04-26

Gültigkeit dieser Erklärung:
von 2021-04-26
bis 2024-05-26

Validity of this declaration:
from 2021-04-26
until 2024-05-26

Mirandola, *26/04/2021*

Francesco Benatti
Head of CoE Renal & WOC Consumables

Mirandola, *2021-04-26*

Chiara Bergamini
Head of Division RA

Anlage I / Attachment I

Art. No.	Brand Name	Description	For	Model	Class	Rule
7211245	DiaStream®	A/V Bloodline Systems for Haemodialysis	Dialog+	HD	Ila	2
7211248	Diastream®	A/V Bloodline Systems for Haemodialysis	Dialog+, FMC 2008-4008, Gambro AK 100-200	HD	Ila	2
7211252	Diastream®	A/V Bloodline Systems for Haemodialysis – Venous line	Dialog+, FMC 2008-4008, Gambro AK 100-200, Nipro Surdial	HD	Ila	2
7211253	Diastream®	A/V Bloodline Systems for Haemodialysis	Dialog+	HD	Ila	2
7211255	DiaStream®	A/V Bloodline Systems for Haemodialysis	Dialog+, FMC 2008-4008, Gambro AK 100-200, Nipro Surdial	HD	Ila	2
7211270	DiaStream®	A/V Bloodline Systems for Haemodialysis	Dialog+	SN	Ila	2
7211271	DiaStream®	A/V Bloodline Systems for Haemodialysis	Dialog+	SNCO	Ila	2
7211272	DiaStream®	A/V Bloodline Systems for Haemodialysis	Dialog+	SNCO	Ila	2
7211273	DiaStream®	A/V Bloodline Systems for Haemodialysis	Gambro AK 100-200	HD	Ila	2
7211274	DiaStream®	A/V Bloodline Systems for Haemodialysis	FMC 2008-4008	HD	Ila	2
7211275	DiaStream®	A/V Bloodline Systems for Haemodialysis	Gambro AK 100-200	SN	Ila	2
7211276	DiaStream®	A/V Bloodline Systems for Haemodialysis	FMC SN 2008-4008	SN	Ila	2
7211277	DiaStream®	A/V Bloodline Systems for Haemodialysis	NIKKISO DBB 03-05-07	HD	Ila	2
7211278	DiaStream®	A/V Bloodline Systems for Haemodialysis	NIKKISO DBB 03-05-07	SN	Ila	2
7211279	DiaStream®	A/V Bloodline Systems for Haemodialysis	Gambro AK 100-200	HD	Ila	2
7211280	DiaStream®	A/V Bloodline Systems for Haemodialysis	FMC 2008-4008	HD	Ila	2

Mirandola, 26/04/2024



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Head of CoE Renal & WOC Consumables

Mirandola, 20/04/2024



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Head of Division RA

7211281	DiaStream®	A/V Bloodline Systems for Haemodialysis	Gambro AK 100-200	SN	Ila	2
7211282	DiaStream®	A/V Bloodline Systems for Haemodialysis	FMC 2008-4008	SN	Ila	2
7211283	DiaStream®	A/V Bloodline Systems for Haemodialysis	Gambro AK 100-200	HDF	Ila	2
7211348	DiaStream®	A/V Bloodline Systems for Haemodialysis	Dialog+	HD	Ila	2
7211349	DiaStream®	A/V Bloodline Systems for Haemodialysis	Dialog+	SNCO	Ila	2
7211350	DiaStream®	A/V Bloodline Systems for Haemodialysis	Dialog+	HD	Ila	2
7211351	DiaStream®	A/V Bloodline Systems for Haemodialysis	Dialog+	HDF	Ila	2
7211352	DiaStream®	A/V Bloodline Systems for Haemodialysis	Dialog+	HD	Ila	2
7211353	DiaStream®	A/V Bloodline Systems for Haemodialysis	Dialog+	HD	Ila	2
7211354	DiaStream®	A/V Bloodline Systems for Haemodialysis	Dialog+	HD	Ila	2
7211355	DiaStream®	A/V Bloodline Systems for Haemodialysis	Dialog+	HD	Ila	2
7211356	DiaStream®	A/V Bloodline Systems for Haemodialysis	Dialog+	HD	Ila	2
7211508	DiaStream® Basic	A/V Bloodline Systems for Hemodialysis	Dialog+	HD	Ila	2
7211509	DiaStream® Classic	A/V Bloodline Systems for Hemodialysis	Dialog+	HD	Ila	2
7211510	DiaStream® Advanced	A/V Bloodline Systems for Hemodialysis	Dialog+	HD	Ila	2
7211511	DiaStream® Premium	A/V Bloodline Systems for Hemodialysis	Dialog+	HD	Ila	2
7211512	DiaStream® Classic	A/V Bloodline Systems for Hemodialysis	Dialog+	HDF	Ila	2
7211513	DiaStream® Classic Universal	A/V Bloodline Systems for Hemodialysis	Dialog+, FMC 2008-4008, Gambro AK 100-200, Nipro Surdial	HD	Ila	2
7211557	DiaStream® Basic	A/V Bloodline Systems for Hemodialysis	Dialog+	HD	Ila	2
7211558	DiaStream® Classic	A/V Bloodline Systems for Hemodialysis	Dialog+	HD	Ila	2


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7211559	DiaStream® Advanced	A/V Bloodline Systems for Hemodialysis	Dialog+	HD	Ila	2
7211560	DiaStream® Premium	A/V Bloodline Systems for Hemodialysis	Dialog+	HD	Ila	2
7211561	DiaStream® Classic	A/V Bloodline Systems for Hemodialysis	Dialog+	HDF	Ila	2
7211562	DiaStream® Classic Universal	A/V Bloodline Systems for Hemodialysis	Dialog+, FMC 2008-4008, Gambro AK 100- 200, Nipro Surdial	HD	Ila	2

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