

Wir

We

B. Braun Avitum AG
Schwarzenberger Weg 73-79
34212 Melsungen
Germanyerklären in eigener Verantwortung,
dass das/die Produkt/e**Dialog+**

SW V9.x

(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinien
übereinstimmt/übereinstimmen:Richtlinie 93/42/EWG des Rates vom 14. Juni 1993
über Medizinprodukte**Konformitätsbewertungsverfahren:**nach Anhang II Absatz 3
der Richtlinie 93/42/EWG**Klassifizierung**gemäß Anhang IX der oben Richtlinie 93/42/EWG:
Klasse IIb, Regel 11**EG-Zertifikat Nr.**

G1 066097 0096 Rev. 02

Benannte Stelle:TÜV SÜD Product Service GmbH
Ridler Straße 65
80339 München
Deutschland
Kennnummer 0123**Datum der ersten CE-Kennzeichnung:**

2003-09

Doc #: 30/09-RA-Ig

Doc Rev #: 24

Rev date: 2020-06-24

Gültigkeit dieser Erklärung: bis 2024-05-26

hereby declare in our own responsibility
that the product/s**Dialog+**

SW V9.x

(article numbers see attachment I)

is/are in compliance with the following directives:

Council Directive 93/42/EEC of 14 June 1993
on medical devices**Conformity assessment procedure:**according to annex II clause 3
of Council Directive 93/42/EEC**Classification**according to annex IX of Council Directive 93/42/EEC:
Class IIb, rule 11**EC Certificate No.**

G1 066097 0096 Rev. 02

Notified body:TÜV SÜD Product Service GmbH
Ridler Straße 65
80339 Munich
Germany
Identification number 0123**Date of first CE-marking:**

2003-09

Doc #: 30/09-RA-Ig

Doc Rev #: 24

Rev date: 2020-06-24

Validity of this declaration: until 2024-05-26

Melsungen, 2020-06-24


Manfred Herres
Senior Vice President CoE Active Medical Devices

Mirandola, 2020.06.24


Dr. Giuliana Gavioli
Head of Division RA

Anlage I / Attachment I

article code	Device Model					Options																		
	Dialog ⁺ (single pump)	Dialog ⁺ (double pump)	Dialog ⁺ online	Powered 230/240 V	Powered 110/120 V	ABPM	bio.L. RP® Comfort	bio.L. RP® Comf. for C.R.	BIC	DCI	battery power supply	Card Reader	Adimea	staff call	DFF	pump roller 7x10	Crit-Line Interface	ZKV	threefold connector ZKV	Nexadia BSL	CN Plug	WAN-BSL	Night Dialysis	
7102005	X			X																				
710200A	X			X						X														
710200C	X			X				X																
710200H	X			X						X				X										
710200I	X			X				X		X														
710200K	X				X	X																		
710200L	X				X	X		X																
710200N	X			X											X									
710200R	X			X						X				X							X			
710200T	X			X																	X			
710200W	X				X																			
710200S	X				X	X		X				X		X								X		
710200U	X				X	X						X		X								X		
710200X	X				X			X				X		X										
710200Y	X				X	X		X				X												
710201C		X		X				X																

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Head of Division RA

article code	Device Model					Options																		
	Dialog+ (single pump)	Dialog+ (double pump)	Dialog+ online	Powered 230/240 V	Powered 110/120 V	ABPM	bioL. RR® Comfort	bioL. RR® Comf. for C.R.	BIC	DCI	battery power supply	Card Reader	Adimea	staff call	DFF	pump roller 7x10	Crit-Line Interface	ZKV	threefold connector ZKV	Nexadia BSL	CN Plug	WAN-BSL	Night Dialysis	
710201CV	X			X		X			X															
7102072			X	X					X															
710207E			X	X		X			X		X							X						
710207T			X	X					X												X			
710207X			X	X		X			X			X												
710207EV			X		X	X			X		X							X						
7102226						X																		
7105324							X																	
7105171								X																
7107218									X															
7102244										X														
7105230											X													
7102233												X												
7102315													X											
7102102														X										
7102340															X									
7105196																		X						
7102230																				X				

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MDD Declaration of Conformity
(Form)

B. Braun Avitum
IMS Avitum PBU - Melsungen

Form-ID: DIV-QA_02-3-01-11-02M Version: 1.0

Doc-ID: DIV-QA_02-3-07-01-01M Version: 2.0

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article code	Device Model					Options																		
	Dialog+ (single pump)	Dialog+ (double pump)	Dialog+ online	Powered 230/240 V	Powered 110/120 V	ABPM	biol. RP® Comfort	biol. RP® Comf. for C.R.	BIC	DCI	battery power supply	Card Reader	Adimea	staff call	DFF	pump roller 7x10	Crit-Line Interface	ZKV	threefold connector ZKV	Nexadia BSL	CN Plug	WAN-BSL	Night Dialysis	
7102400																						X		
7102231																							X	

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Legend

grey background	Used for Articles Numbers already existing		
blue text	New Article Numbers		
ABPM	Automatic Blood Pressure Measurement	WAN-BSL	Wide Area Network - Bed Side Link -integrated device for the network capability
Adimea	Kt/V measurement by UV light absorption	CN	China
bioL RR Comfort	Automatic blood pressure stabilization (bioL Stands for bioLogic)	DCI	Dialog Computer Interface
bioL RR Comf. For C.R	Use of bioLogic RR Comfort combined with Card Reader (C.R.)	DFF	Dialysis Fluid Filter
BiC	Bicarbonate Cartridge Holder	ZKV	Central Concentrate Supply
BSL	Bed Side Link	threefold connector ZKV	threefold connector Central Concentrate Supply

Refurbished machines

In case of refurbished machines, the corresponding Article Number as listed above is modified by adding at the end of the Article Number itself a letter G.

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OBSOLETE ARTICLE NUMBERS

This Declaration of Conformity covers also the following list of obsolete Article Numbers.
(obsolete = not more produced)

article code	Dialog+ (single pump)	Dialog+ (double pump)	Dialog+ online	Powered 230/240 V	Powered 110/120 V	ABPM	bioL. RR® Comfort	bioL. RR® Comf. for C.R.	BIC	DCI	battery power supply	Card Reader	Adimea	staff call	DFE	pump roller 7x10	Crit-Line Interface	ZKV	threefold connector ZKV	Nexadia BSL	CN Plug	WAN-BSL	Night Dialysis	
710200E	X			X					X									X						
710200F	X			X					X				X											
710200P	X			X		X			X				X								X			
710200CV	X				X	X			X															
710200SV	X				X	X			X		X				X				X		X			
710200ZV	X				X	X			X						X									
710200IV	X				X	X			X		X				X				X					
7102013		X		X																				
710201A		X		X															X					
710201E		X		X					X										X					
710201G		X		X					X		X	X			X				X					
710201I		X		X					X						X				X					
710201S		X		X		X			X		X	X			X				X					
710201T		X		X					X		X	X							X					
710201U		X		X		X			X		X	X							X					
710201EV		X			X	X			X		X				X				X					

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article code	Dialog+ (single pump)	Dialog+ (double pump)	Dialog+ online	Powered 230/240 V	Powered 110/120 V	ABPM	bioL. RR® Comfort	bioL. RR® Comf. for C.R.	BIC	DCI	battery power supply	Card Reader	Adimea	staff call	DFE	pump roller 7x10	Crit-Line Interface	ZKV	threefold connector ZKV	Nexadia BSL	CN Plug	WAN-BSL	Night Dialysis
710201SV	X			X	X	X			X		X				X			X		X			
710201XV	X			X	X	X			X		X				X								
710207D			X	X					X		X	X						X					
710207F			X	X					X				X										
710207P			X	X		X			X				X							X			
710207XV			X		X	X			X		X							X		X			
7105323							X																
7106604																	X						
7102868																			X				
7103315																							X

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