

Wir

We

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

erklären 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

und in Übereinstimmung mit allen anwendbaren
Anforderungen der Verordnung EU 2017/745 Art. 120(3)

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 #: 25

Rev date: 2024-04-23

Gültigkeit dieser Erklärung: bis 2024-05-26

Melsungen, 2024-04-24

Dr. Jörn Meibaum

Vice President CoE Active Medical Devices

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

and is/are in compliance with all the applicable
requirements of Regulation EU 2017/745 art. 120(3)

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 #: 25

Rev date: 2024-04-23

Validity of this declaration: until 2024-05-26

Mirandola, 2024-04-23

Chiara Bergamini

Vice President Regulatory Affairs

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	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	
7102005	X			X						X														
710200A	X			X				X																
710200C	X			X				X		X														
710200H	X			X				X		X					X									
710200I	X			X				X		X														
710200K	X			X			X	X																
710200L	X			X			X	X																
710200N	X			X			X	X								X								
710200R	X			X			X	X		X					X						X			
710200T	X			X			X	X		X					X						X			
710200W	X			X			X	X		X														
710200S	X			X			X	X		X			X		X							X		
710200U	X			X			X	X		X			X		X							X		
710200X	X			X			X	X		X			X		X									
710200Y	X			X			X	X		X			X		X									
710201C	X			X			X	X		X			X		X									

Melsungen, 2024-04-24



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Mirandola, 2024-04-23



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710201CV	X			X	X	X		X																
7102072		X	X	X		X		X		X								X						
710207E			X	X		X		X		X														
710207T			X	X		X		X		X											X			
710207X			X	X		X		X		X														
710207EV			X	X		X		X		X								X						
710207F			X	X		X		X		X														
7102226						X																		
7105324																								
7105171								X																
7107218									X															
7102244										X														
7105230											X													
7102233												X												
7102315													X											
7102102														X										
7102340															X									
7105196																X								

Melsungen, 2024-04-24

 Dr. Jörn Meibäum
 Vice President CoE Active Medical Devices

Mirandola, 2024-04-23

 Chiara Bergamini
 Vice President Regulatory Affairs



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
Page: 4 of 7

Table with columns: article code, Device Model, Options. Rows include article codes 7102230, 7102400, 7102231 and various device models like Dialog+, ABPM, and options like Nexadia BSL, CN Plug, WAN-BSL, Night Dialysis.

Melsungen, 2024-04-24
Signature of Dr. Jörn Meißbaum
Dr. Jörn Meißbaum
Vice President CoE Active Medical Devices

Mirandola, 2024-04-23
Signature of Chiara Bergamini
Chiara Bergamini
Vice President Regulatory Affairs

Legend

grey background blue text	Used for Articles Numbers already existing 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.)	DFE 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.

Melsungen, 2024-04-24

Dr. Jörn Meibaum
Vice President CoE Active Medical Devices

Mirandola, 2024-04-23

Chiara Bergamini
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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	DFP	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		X							X		X				
710200SV	X				X	X			X						X									
710200ZV	X				X	X			X		X				X									
710200IV	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						
710201I		X			X				X		X				X			X						
710201S		X			X		X		X		X				X			X						
710201T		X			X				X		X				X			X						
710201U		X			X				X		X				X			X						
710201EV		X			X				X		X				X			X						

Melsungen, 2024-04-24

Mirandola, 2024-04-23

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Chiara Bergamini
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MDD Declaration of Conformity
(Form)

B. Braun Avitum
IMS Avitum PBU - Melsungen

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Page: 7 of 7

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710201SV	X				X	X			X		X				X			X		X			
710201XV	X				X	X			X		X				X			X		X			
710207D		X	X	X					X		X							X					
710207P		X	X	X		X			X		X							X		X			
710207XV		X	X	X		X	X		X		X							X		X			
7105323																							
7106604																							
7102868							X																
7103315																							X

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