

Wir

We

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

erklären in eigener Verantwortung,  
dass das/die Produkt/e

**Dialog<sup>+</sup>**

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<sup>+</sup>**

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

Melsungen, 2024-04-24



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710201CV	X				X	X		X															
7102072		X	X	X		X		X		X								X					
710207E			X	X		X		X		X											X		
710207T			X	X		X		X															
710207X			X	X		X		X															
710207EV			X	X	X	X		X		X								X					
710207F			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+, Powered, ABPM, and options like staff call, DFF, pump roller 7x10, etc.

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 <b>blue text</b>	Used for Articles Numbers already existing <b>New Article Numbers</b>		
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



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Mirandola, 2024-04-23



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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				
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					

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MDD Declaration of Conformity  
(Form)

B. Braun Avitum  
IMS Avitum PBU - Melsungen

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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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