

**Konformitätserklärung
Declaration of Conformity**

Wir

We

**B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany**erklären in eigener Verantwortung,
dass das/die Produkt/e**Drain de Redon,
Drainocont,
Redon,
Redon Nadel**
Redon Drains**variabler Drainverbinder,
Redon-Verbindungsschlauch**
Redon Verbindungen

(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmenRichtlinie 93/42/EWG des Rates vom 14. Juni
1993über Medizinprodukte
geändert durch Richtlinie 2007/47/EG**Konformitätsbewertungsverfahren**
nach Anhang II (ausgenommen Abschnitt 4)
der oben genannten Richtlinie**Klassifizierung**
gemäß Anhang IX der
oben genannten Richtlinie
Klasse IIa**Benannte Stelle**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123**Datum der ersten CE-Kennzeichnung**
1994-12**Gültig bis**
2024-05-26hereby declare in our own responsibility
that the product/s**Drain de Redon,
Drainocont,
Redon,
Redon Nadel**
Redon Drains**variabler Drainverbinder,
Redon-Verbindungsschlauch**
Redon Connections

(article numbers see attachment I)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14th June
1993concerning Medical Devices
amended by Directive 2007/47/EC**Conformity Assessment Procedure**
according to annex II (excluding section 4)
of the Council Directive named above**Classification**
according to annex IX of the
Council Directive named above
Class IIa**Notified Body**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123**Date of first CE-marking**
1994-12**Valid until**
2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
5524911	Redon-Verbindungsschlauch	Ila
5524920	Redon-Verbindungsschlauch	Ila
5524989	variabler Drainverbinder	Ila
5526639	Redon Nadel	Ila
5526868	Redon Nadel	Ila
5526876	Redon Nadel	Ila
5526884	Redon Nadel	Ila
5526892	Redon Nadel	Ila
5528208	Drainocont	Ila
5528218	Drainocont	Ila
5528224	Drainocont	Ila
5528232	Drainocont	Ila
5528240	Drainocont	Ila
5528302	Drainocont	Ila
5528313	Drainocont	Ila
5528321	Drainocont	Ila
5528330	Drainocont	Ila
5528340	Drainocont	Ila
94610	Drain de Redon	Ila
94615	Drain de Redon	Ila
94620	Drain de Redon	Ila
94625	Drain de Redon	Ila
94630	Drain de Redon	Ila
94635	Drain de Redon	Ila
94645	Drain de Redon	Ila
U2110600	Redon	Ila
U2110800	Redon	Ila
U2111000	Redon	Ila
U2111200	Redon	Ila
U2111400	Redon	Ila
U2111600	Redon	Ila
U2111800	Redon	Ila
U2170701	Redon-Verbindungsschlauch	Ila

Amendment Information

Version	Description of the changes
10	Delete Out of Market art. no. 5524946, U2101402, U2101602, U2110602
11	Delete Out of Market art. no. 5525047
12	Delete Out of Market art. no. 901820, 901835, U2111402, 5524903
13	Delete Out of Market art. no. 5524954
14	Delete Out of Market art. no. U2101602, 5524938

Title: Declaration of Conformity - 39.05.304 - Redon Initiator: Caroline ? Herbst

This document is signed electronically in compliance with the B. Braun electronic signature policies and procedures by following persons:

UserName: Herbst, Caroline (fuehcade)
Title: Administrator Regulatory Affairs
Date: Thursday, 09 April 2020, 10:20 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Thursday, 09 April 2020, 11:06 W. Europe Daylight Time
Meaning: Approve Document

UserName: Seidel, Stefan (seidstde)
Title: HC-RA-DE08E - Head of Regulatory Affairs CoE IV Systems
Date: Thursday, 09 April 2020, 15:58 W. Europe Daylight Time
Meaning: Approve Document
