

**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/ehereby declare in our own responsibility
that the product/s**Drain silicone,
Drainagekatheter für Laparotomie,
Robdrain®****Drain silicone,
Drainagekatheter für Laparotomie,
Robdrain®**

Geschlossene Wunddrainage

Closed gravity wound drainage

(Artikelnummern siehe Anlage I)

(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
geändert durch Richtlinie 2007/47/EGCouncil Directive 93/42/EEC of 14th June
1993
concerning Medical Devices
amended by Directive 2007/47/EC**Konformitätsbewertungsverfahren**
nach Anhang II (ausgenommen Abschnitt 4)
der oben genannten Richtlinie**Conformity Assessment Procedure**
according to annex II (excluding section 4)
of the Council Directive named above**Klassifizierung**
gemäß Anhang IX der
oben genannten Richtlinie
Klasse IIa**Classification**
according to annex IX of the
Council Directive named above
Class IIa**Benannte Stelle**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123**Notified Body**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123**Datum der ersten CE-Kennzeichnung**
1997-09**Date of first CE-marking**
1997-09**Gültig bis**
2024-05-26**Valid until**
2024-05-26

Anlage I / Attachment I

Art.-Nr. /Art. No.	Produktname / Product name	Klasse / Class
0068824J	Drain silicone	Ila
0068825K	Drain silicone	Ila
0068826L	Drain silicone	Ila
0068827M	Drain silicone	Ila
0068828N	Drain silicone	Ila
B68830	Drain silicone	Ila
B68831	Drain silicone	Ila
B68832	Drain silicone	Ila
B68833	Drain silicone	Ila
U2251800	Drainagekatheter für Laparotomie	Ila
U2252200	Drainagekatheter für Laparotomie	Ila
U2252500	Drainagekatheter für Laparotomie	Ila
U2252700	Drainagekatheter für Laparotomie	Ila
U2253000	Drainagekatheter für Laparotomie	Ila
U2253200	Drainagekatheter für Laparotomie	Ila
U2261210	Robdrain®	Ila
U2261410	Robdrain®	Ila
U2261610	Robdrain®	Ila
U2262010	Robdrain®	Ila
U2262410	Robdrain®	Ila
U2262610	Robdrain®	Ila
U2263010	Robdrain®	Ila

Amendment Information

Version	Description of the changes
07	Delete Out of Market art. no. 0068829P, B68834
08	Delete Out of Market art. no. B75872, B75873, B75876
09	Delete Out of Market art. no. B75874
10	Delete Out of Market art. no. B75875
11	Update validity

Title: Declaration of Conformity - 39.05.307 - Robdrain Initiator: Caroline ? Herbst

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

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Title: Administrator Regulatory Affairs
Date: Thursday, 09 April 2020, 10:21 W. Europe Daylight Time
Meaning: Document signed as Author

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Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Thursday, 09 April 2020, 10:43 W. Europe Daylight Time
Meaning: Approve Document

UserName: Seidel, Stefan (seidstde)
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Date: Thursday, 09 April 2020, 15:58 W. Europe Daylight Time
Meaning: Approve Document
