

**Konformitätserklärung
Declaration of Conformity**

Wir

We

**B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Deutschland/Germany
SRN DE-MF-000000201**erklären in eigener Verantwortung,
dass das Produkt / die Produkte**Drainobag® Lock 600, Drainobag® Basse
Pression, Drainobag® Lock 300,
Drainobag® 150, Drainobag® Lock 150**
Vakuum-Wunddrainage-System nach Redon
ohne Verbindungsschlauch
Basis UDI-DI: 403923900000281736
(Artikelnummern siehe Anlage I)**Drainobag® 600 V, Drainobag® Lock 600 V,
Drainobag® Basse Pression TL,
Drainobag® 300 V, Drainobag® Lock 300 V,
Drainobag® Lock 300 V, Drainobag® 150 V,
Drainobag® 150 VL, Drainobag® Lock 150
V, Drainobag® Lock 150 VL, Drainobag®
400 V**
Vakuum-Wunddrainage-System nach Redon mit
Verbindungsschlauch
Basis UDI-DI: 40392390000007973B
(Artikelnummern siehe Anlage I)mit den Anforderungen der Medizinprodukte
Verordnung (EU) 2017/745 übereinstimmen**Konformitätsbewertungsverfahren**
nach Anhang IX
der oben genannten Verordnung**Klassifizierung**
gemäß Anhang VIII der oben genannten
Verordnung
Klasse IIahereby declare in our sole responsibility
that the product/s**Drainobag® Lock 600, Drainobag® Basse
Pression, Drainobag® Lock 300,
Drainobag® 150, Drainobag® Lock 150**
Vacuum wound drainage system according to
Redon without connection tube
Basic UDI-DI: 403923900000281736
(article numbers see attachment I)**Drainobag® 600 V, Drainobag® Lock 600 V,
Drainobag® Basse Pression TL,
Drainobag® 300 V, Drainobag® Lock 300 V,
Drainobag® Lock 300 V, Drainobag® 150 V,
Drainobag® 150 VL, Drainobag® Lock 150
V, Drainobag® Lock 150 VL, Drainobag®
400 V**
Vacuum wound drainage system according to
Redon with connection tube
Basic UDI-DI: 40392390000007973B
(article numbers see attachment I)are in conformity with the requirements of the
Medical Device Regulation (EU) 2017/745**Conformity Assessment Procedure**
according to annex IX
of the Regulation named above**Classification**
according to annex VIII of the Regulation named
above
Class IIa

Benannte StelleTÜV SÜD Product Service GmbH
Kennnummer 0123**Gültig bis**gemäß gültigem EU Zertifikat
(G10 012974 0611)**Notified Body**TÜV SÜD Product Service GmbH
Identification number 0123**Valid until**according to our valid EU Certificate
(G10 012974 0611)

Anlage I / Attachment I**Basic UDI-DI 403923900000281736**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
5523682	Drainobag® Lock 600	Ila
5524237	Drainobag® Basse Pression	Ila
5522390	Drainobag® Lock 300	Ila
5523753	Drainobag® 150	Ila
5523761	Drainobag® Lock 150	Ila
55237611	Drainobag® Lock 150	Ila

Basic UDI-DI 40392390000007973B

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
5523605	Drainobag® 600 V	Ila
5523606	Drainobag® 600 V	Ila
5523648	Drainobag® Lock 600 V	Ila
5523649	Drainobag® Lock 600 V	Ila
5524210	Drainobag® Basse Pression TL	Ila
5522322	Drainobag® 300 V	Ila
5522340	Drainobag® Lock 300 V	Ila
55223401	Drainobag® Lock 300 V	Ila
5523702	Drainobag® 150 V	Ila
5523710	Drainobag® 150 VL	Ila
5523729	Drainobag® Lock 150 V	Ila
5523737	Drainobag® Lock 150 VL	Ila
55237371	Drainobag® Lock 150 VL	Ila
5523601	Drainobag® 400 V	Ila

Document amendment information

Version	Description of the changes
1.0	Initial Version under 2017/745 MDR

Title: Declaration of Conformity - 002-001-MDR - Drainobag Initiator: Susanne ? Olbricht

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

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Meaning: Document signed as Author

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