

**Konformitätserklärung
Declaration of Conformity**

Wir

We

**B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Deutschland/Germany
DE-MF-00000201**erklären in eigener Verantwortung,
dass das/die Produkt/e**Rectobag®**Spülungs- und Auffangbeutel
Basis UDI-DI: 4039239000001882C
(Artikelnummern siehe Anlage I)mit den Anforderungen der Medizinprodukte
Verordnung (EU) 2017/745
übereinstimmt/übereinstimmen**Konformitätsbewertungsverfahren**
nach Artikel 52 Absatz 7 der oben genannten
Verordnung**Klassifizierung**gemäß Anhang VIII der oben genannten
Verordnung
Klasse I**Gültig bis**gemäß gültigem ISO Zertifikat (Nr. Q5 022239 0095)
(Klasse I Produkte)hereby declare in our own responsibility
that the product/s**Rectobag®**Irrigation and collection bag
Basic UDI-DI: 4039239000001882C
(article numbers see attachment I)is/are in conformity with the requirements of the
Medical Device Regulation (EU) 2017/745**Conformity Assessment Procedure**
according to article 52 section 7
of the Regulation named above**Classification**according to annex VIII of the Regulation named
above
Class I**Valid until**according to our valid ISO Certificate (No. Q5 022239
0095) (class I devices)

Anlage I / Attachment I

Basic UDI-DI : 40392390000001882C

Art.-Nr. / Art. No.	Produktname / Product name
4423356	Rectobag®

Klasse / Class
I NS

Document amendment information

Version	Description of the changes
1.0	Initial Declaration of Conformity in compliance with MDR (EU) 2017/745
2.0	Update of the document following renewal of ISO 13485 certificate
3.0	Update of the document following renewal of ISO 13485 certificate

Title: 007-003-7.1 Rectobag Non Sterile Initiator: Priscilla ? Chapelier

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

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