

**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 die Produkte**Mini-Spike® Filter, Mini-Spike®, Mini-Spike® Chemo, Mini-Spike® Micro-Tip, Mini-Spike® Filter Micro-Tip, Mini-Spike® Chemo Micro-Tip, Mini-Spike® V, Mini-Spike® Filter V, Mini-Spike® Chemo V, Mini-Spike® 2, Mini-Spike® 2 Filter, Mini-Spike® 2 Chemo, Mini-Spike® 2 Micro-Tip, Mini-Spike® 2 Filter Micro-Tip, Mini-Spike® 2 Chemo Micro-Tip**

Entnahme- und Zuspritzspike für Einzel- und Mehrdosenfläschchen

Basis UDI-DI: 4039239000000270ZT
(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 I steril**Benannte Stelle**
TÜV SÜD Product Service GmbH
Kennnummer 0123**Gültig bis**
gemäß gültigem EU Zertifikat
(Nr. G11 012974 0626)hereby declare in our sole responsibility
that the products**Mini-Spike® Filter, Mini-Spike®, Mini-Spike® Chemo, Mini-Spike® Micro-Tip, Mini-Spike® Filter Micro-Tip, Mini-Spike® Chemo Micro-Tip, Mini-Spike® V, Mini-Spike® Filter V, Mini-Spike® Chemo V, Mini-Spike® 2, Mini-Spike® 2 Filter, Mini-Spike® 2 Chemo, Mini-Spike® 2 Micro-Tip, Mini-Spike® 2 Filter Micro-Tip, Mini-Spike® 2 Chemo Micro-Tip**

Removal and injection spikes for single- and multi-dose vials

Basic UDI-DI: 4039239000000270ZT
(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 I sterile**Notified Body**
TÜV SÜD Product Service GmbH
Identification number 0123**Valid until**
according to our valid EU Certificate
(No. G11 012974 0626)

Anlage I / Attachment I**Basic UDI-DI 4039239000000270ZT**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4550234	Mini-Spike® Filter	I steril / I sterile
4550242	Mini-Spike®	I steril / I sterile
4550340	Mini-Spike® Chemo	I steril / I sterile
4550340-04	Mini-Spike® Chemo	I steril / I sterile
4550340BR	Mini-Spike® Chemo	I steril / I sterile
4550510	Mini-Spike® Micro-Tip	I steril / I sterile
4550528	Mini-Spike® Filter Micro-Tip	I steril / I sterile
4550536	Mini-Spike® Chemo Micro-Tip	I steril / I sterile
4550560	Mini-Spike® V	I steril / I sterile
4550560-04	Mini-Spike® V	I steril / I sterile
4550560IN	Mini-Spike® V	I steril / I sterile
4550579	Mini-Spike® Filter V	I steril / I sterile
4550579-04	Mini-Spike® Filter V	I steril / I sterile
4550579PE	Mini-Spike® Filter V	I steril / I sterile
4550587	Mini-Spike® Chemo V	I steril / I sterile
4550587-04	Mini-Spike® Chemo V	I steril / I sterile
4550587PE	Mini-Spike® Chemo V	I steril / I sterile
4550590	Mini-Spike® 2	I steril / I sterile
4550591	Mini-Spike® 2 Filter	I steril / I sterile
4550592	Mini-Spike® 2 Chemo	I steril / I sterile
4550593	Mini-Spike® 2 Micro-Tip	I steril / I sterile
4550594	Mini-Spike® 2 Filter Micro-Tip	I steril / I sterile
4550595	Mini-Spike® 2 Chemo Micro-Tip	I steril / I sterile

Document amendment information

Version	Description of the changes
1.0	Initial Version under 2017/745 MDR based on change HC-CHC-M-DIV-2296
2.0	Addition of article no. 4550340BR, 4550579PE, and 4550587PE as well as update of the intended purpose based on project ACTIVE F3 (with corresponding change controls HC-CHC-M-DIV-2459 and HC-CHC-M-DIV-2537). Minor editorial adaptations.

Title: Declaration of Conformity - 214-300-MDR - Mini-Spike Initiator: Jascha T Manschwetus

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

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