

**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 Zuspritzspikes für  
MehrdosenbehälterBasis 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  
(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 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  
(G11 012974 0626)

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

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
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
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
4550587	Mini-Spike® Chemo V	I steril / I sterile
4550587-04	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

Title: Declaration of Conformity - 214-300-MDR - Mini-Spike 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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