# 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

**Mini Spike Plus 6/8 R**
Transfersystem für Vials

Basis UDI-DI: 40392390000027212Q
(Artikelnummern siehe Anlage I)

mit den Anforderungen der Medizinprodukte Verordnung (EU) 2017/745 übereinstimmt

**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 product

**Mini Spike Plus 6/8 R**
Transfer system for vials

Basic UDI-DI: 40392390000027212Q
(article numbers see attachment I)

is 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)

Effective

## Anlage I / Attachment I

**Basic UDI-DI 40392390000027212Q**

| Art.-Nr. / Art. No. | Produktname / Product name | Klasse / Class |
|---|---|---|
| 4550315 | Mini Spike Plus 6/8 R | I steril / I sterile |

Effective

**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 - 214-301-MDR - Mini Spike Plus 6-8 R 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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