

Konformitätserklärung**Declaration of Conformity**

Wir

We

**B. Braun Melsungen AG
Carl-Braun-Straße 1
34212 Melsungen
Deutschland/Germany**

erklären in eigener Verantwortung,
dass das/die Produkt/e

**Mini-Spike[®],
Mini-Spike[®] V,
Mini-Spike[®] Plus,
Mini-Spike[®] 2,
Mini-Spike[®] Filter,
Mini-Spike[®] 2 Filter,
Mini-Spike[®] Filter V,
Mini-Spike[®] Filter Micro-Tip,
Mini Spike[®] Plus 6/8 R,
Mini-Spike[®] Chemo,
Mini-Spike[®] 2 Chemo,
Mini-Spike[®] Chemo V,
Mini-Spike[®] Chemo Micro-Tip,
Mini-Spike[®] Micro-Tip,
Sterifix[®] Mini Spike[®]**

Entnahme- und Zuspritzspikes für
Mehrdosenbehälter

(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmen

Richtlinie 93/42/EWG des Rates vom 14. Juni 1993
über Medizinprodukte
geändert durch Richtlinie 2007/47/EG

Konformitätsbewertungsverfahren
nach Anhang VII und V
der oben genannten Richtlinie

Klassifizierung
gemäß Anhang IX der
oben genannten Richtlinie
Klasse I steril

Benannte Stelle
TÜV SÜD Product Service GmbH
Kennnummer 0123

hereby declare in our own responsibility
that the product/s

**Mini-Spike[®],
Mini-Spike[®] V,
Mini-Spike[®] Plus,
Mini-Spike[®] 2,
Mini-Spike[®] Filter,
Mini-Spike[®] 2 Filter,
Mini-Spike[®] Filter V,
Mini-Spike[®] Filter Micro-Tip,
Mini Spike[®] Plus 6/8 R,
Mini-Spike[®] Chemo,
Mini-Spike[®] 2 Chemo,
Mini-Spike[®] Chemo V,
Mini-Spike[®] Chemo Micro-Tip,
Mini-Spike[®] Micro-Tip,
Sterifix[®] Mini Spike[®]**

Withdrawal and injection spikes for
multidose vials

(article numbers see attachment I)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14th June 1993
concerning Medical Devices
amended by Directive 2007/47/EC

Conformity Assessment Procedure
according to annex VII and V
of the Council Directive named above

Classification
according to annex IX of the
Council Directive named above
Class I sterile

Notified Body
TÜV SÜD Product Service GmbH
Identification number 0123

Konformitätserklärung**Declaration of Conformity****Datum der ersten CE-Kennzeichnung**

Mini-Spike® Plus	1994-12
Mini Spike® Plus 6/8 R	1994-12
Mini-Spike® V	1994-12
Sterifix® Mini Spike®	1994-12
Mini-Spike®	2008-09
Mini-Spike® Filter	2008-09
Mini-Spike® Chemo	2008-09
Mini-Spike® Micro-Tip	2008-09
Mini-Spike® Filter Micro-Tip	2008-09
Mini-Spike® Chemo Micro-Tip	2008-09
Mini-Spike® Filter V	2008-09
Mini-Spike® Chemo V	2008-09
Mini-Spike® 2	2013-10
Mini-Spike® 2 Chemo	2013-10
Mini-Spike® 2 Filter	2013-10

Date of first CE-marking

Mini-Spike® Plus	1994-12
Mini Spike® Plus 6/8 R	1994-12
Mini-Spike® V	1994-12
Sterifix® Mini Spike®	1994-12
Mini-Spike®	2008-09
Mini-Spike® Filter	2008-09
Mini-Spike® Chemo	2008-09
Mini-Spike® Micro-Tip	2008-09
Mini-Spike® Filter Micro-Tip	2008-09
Mini-Spike® Chemo Micro-Tip	2008-09
Mini-Spike® Filter V	2008-09
Mini-Spike® Chemo V	2008-09
Mini-Spike® 2	2013-10
Mini-Spike® 2 Chemo	2013-10
Mini-Spike® 2 Filter	2013-10

Gültig bis

2020-08-21

Valid until

2020-08-21

Melsungen, 2015-08-21

Melsungen, 2015-08-21

B. Braun Melsungen AG

B. Braun Melsungen AG

i. V.



Thomas Stefan Brand

Vice President Quality Management for non-active Medical Devices

i. V.



Dr. Stefan Seidel

Head of Regulatory Affairs CoE IV-Systems

Konformitätserklärung**Declaration of Conformity****Anlage I / Attachment I**

Art.-Nr. / Art. No.	Produktname/ Product name	Klasse / Class
4550226	Sterifix® Mini Spike®	I steril / I sterile
4550234-04	Mini-Spike® Filter	I steril / I sterile
4550234	Mini-Spike® Filter	I steril / I sterile
4550242-04	Mini-Spike®	I steril / I sterile
4550242	Mini-Spike®	I steril / I sterile
4550315	Mini Spike® Plus 6/8 R	I steril / I sterile
4550340-04	Mini-Spike® Chemo	I steril / I sterile
4550340	Mini-Spike® Chemo	I steril / I sterile
4550510-04	Mini-Spike® Micro-Tip	I steril / I sterile
4550510	Mini-Spike® Micro-Tip	I steril / I sterile
4550528-04	Mini-Spike® Filter Micro-Tip	I steril / I sterile
4550528	Mini-Spike® Filter Micro-Tip	I steril / I sterile
4550536-04	Mini-Spike® Chemo Micro-Tip	I steril / I sterile
4550536	Mini-Spike® Chemo Micro-Tip	I steril / I sterile
4550560-04	Mini-Spike® V	I steril / I sterile
4550560	Mini-Spike® V	I steril / I sterile
4550579-04	Mini-Spike® Filter V	I steril / I sterile
4550579	Mini-Spike® Filter V	I steril / I sterile
4550587-04	Mini-Spike® Chemo V	I steril / I sterile
4550587	Mini-Spike® Chemo V	I steril / I sterile
4550590	Mini-Spike® 2	I steril / I sterile
4550590-04	Mini-Spike® 2	I steril / I sterile
4550591	Mini-Spike® 2 Filter	I steril / I sterile
4550591-04	Mini-Spike® 2 Filter	I steril / I sterile
4550592	Mini-Spike® 2 Chemo	I steril / I sterile
4550592-04	Mini-Spike® 2 Chemo	I steril / I sterile
9209344	Mini-Spike® Plus	I steril / I sterile
9209360	Mini-Spike® Plus	I steril / I sterile
9209379	Mini-Spike® Plus	I steril / I sterile