

## 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® 2 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

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® 2 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 14<sup>th</sup> 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

**Benannte Stelle**

TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 München  
Deutschland  
Kennnummer 0123

**Datum der ersten CE-Kennzeichnung**

Mini-Spike® Plus	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
Mini-Spike® 2 Chemo Micro-Tip	2020-02

**Gültig bis**

2024-05-26

**Notified Body**

TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 München  
Germany  
Identification number 0123

**Date of first CE-marking**

Mini-Spike® Plus	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
Mini-Spike® 2 Chemo Micro-Tip	2020-02

**Valid until**

2024-05-26

**Anlage I / Attachment I**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname/ Product name</b>	<b>Klasse / Class</b>
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
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
4550560IN	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
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
9209344	Mini-Spike® Plus	I steril / I sterile
9209360	Mini-Spike® Plus	I steril / I sterile
9209379	Mini-Spike® Plus	I steril / I sterile

**Amendment Information**

Version	Description of changes
15.0	Add art. no. 4550560IN
16.0	Add art. no. 4550234-20, 4550242-20, 4550340-20, 4550510-20, 4550528-20, 4550536-20, 4550560-20, 4550579-20, 4550587-20 Delete art. no. 4550590-04, 4550591-04, 4550592-04
17.0	Add art. no. 4550595
18.0	Add art. no. 4550593, 4550594 Delete art. no. 4550234-20, 4550242-20, 4550340-20, 4550510-20, 4550528-20, 4550536-20, 4550560-20, 4550579-20, 4550587-20 that will not be produced
19.0	Delete art. no. 4550315 which will be covered by DoC 214-301

Title: Declaration of Conformity - 39.05.004 - Mini-Spike Initiator: Caroline ? Herbst

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

UserName: Herbst, Caroline (fuehcade)  
Title: Administrator Regulatory Affairs  
Date: Friday, 07 May 2021, 16:34 W. Europe Daylight Time  
Meaning: Document signed as Author  
=====

UserName: Seidel, Stefan (seidstde)  
Title: HC-RA-DE08E - Head of Regulatory Affairs CoE IV Systems  
Date: Friday, 07 May 2021, 17:31 W. Europe Daylight Time  
Meaning: Approve Document  
=====

UserName: Brand, Thomas (brantode)  
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices  
Date: Friday, 07 May 2021, 17:34 W. Europe Daylight Time  
Meaning: Approve Document  
=====