

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 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

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

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
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
=====