

**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**Sterican®
EXTAVIA® Sterican® 30G
LUCENTIS® Sterican® 30G
ExtaviPro® Sterican® 30G**

Einmalkanülen

(Artikelnummern siehe Anlage I)

mit den Anforderungen der folgenden Richtlinie
übereinstimmt/übereinstimmenRichtlinie 93/42/EWG des Rates vom 14. Juni
1993
über Medizinprodukte
geändert durch Richtlinie 2007/47/EG**Konformitätsbewertungsverfahren**
nach Anhang II (ausgenommen Abschnitt 4)
der oben genannten Richtlinie**Klassifizierung**
gemäß Anhang IX der
oben genannten Richtlinie
Klasse IIa**Benannte Stelle**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123**Datum der ersten CE-Kennzeichnung**
1994-12**Gültig bis**
2024-05-26hereby declare in our own responsibility
that the product/s**Sterican®
EXTAVIA® Sterican® 30G
LUCENTIS® Sterican® 30G
ExtaviPro® Sterican® 30G**

Hypodermic Needles for Single Use

(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 II (excluding section 4)
of the Council Directive named above**Classification**
according to annex IX of the
Council Directive named above
Class IIa**Notified Body**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123**Date of first CE-marking**
1994-12**Valid until**
2024-05-26

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
2074517	LUCENTIS® Sterican® 30G	Ila
4650018	Sterican®	Ila
4650034	Sterican®	Ila
4656300	Sterican®	Ila
4657500	Sterican®	Ila
4657519	Sterican®	Ila
4657527	Sterican®	Ila
4657543	Sterican®	Ila
4657624	Sterican®	Ila
4657640	Sterican®	Ila
4657667	Sterican®	Ila
4657675	Sterican®	Ila
4657683	Sterican®	Ila
4657705	Sterican®	Ila
4657788	EXTAVIA® Sterican® 30G	Ila
4657789-01	ExtaviPro® Sterican® 30G	Ila
4657799	Sterican®	Ila
4657853	Sterican®	Ila
4660021	Sterican®	Ila
4665112	Sterican®	Ila
4665120	Sterican®	Ila
4665317	Sterican®	Ila
4665406	Sterican®	Ila
4665457	Sterican®	Ila
4665465	Sterican®	Ila
4665473	Sterican®	Ila
4665503	Sterican®	Ila
4665511	Sterican®	Ila
4665600	Sterican®	Ila
4665635	Sterican®	Ila
4665643	Sterican®	Ila
4665791	Sterican®	Ila
4666410	Sterican®	Ila
4667093	Sterican®	Ila
4667123	Sterican®	Ila
9180109	Sterican®	Ila
9180117	Sterican®	Ila

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
9186158	Sterican®	Ila
9186166	Sterican®	Ila
9186174	Sterican®	Ila
9186182	Sterican®	Ila

Amendment Information

Version	Description of the changes
18	Delete Out of Market art. no. 0086806A, 4053656, 4053665, 4053666, 4053621
19	Delete Out of Market art. no. 4053648
20	Delete Out of Market art. no. 4053605, 4053613, 4053630, 4053664
21	Delete Out of Market art. no. 4660072
22	Update validity

Title: Declaration of Conformity - 39.05.220 - Sterican 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: Monday, 06 April 2020, 07:22 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Monday, 06 April 2020, 10:13 W. Europe Daylight Time
Meaning: Approve Document

UserName: Seidel, Stefan (seidstde)
Title: HC-RA-DE08E - Head of Regulatory Affairs CoE IV Systems
Date: Monday, 06 April 2020, 16:38 W. Europe Daylight Time
Meaning: Approve Document
