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

hereby declare in our own responsibility that the product/s

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

Einmalkanülen

(Artikelnummern siehe Anlage I)

Hypodermic Needles for Single Use

(article numbers see attachment I)

mit den Anforderungen der folgenden Richtlinie übereinstimmt/übereinstimmen

is/are in compliance with the following directive

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

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

Konformitätsbewertungsverfahren
nach Anhang II (ausgenommen Abschnitt 4) der oben genannten Richtlinie

Conformity Assessment Procedure
according to annex II (excluding section 4) of the Council Directive named above

Klassifizierung
gemäß Anhang IX der oben genannten Richtlinie
Klasse IIa

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

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

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

Datum der ersten CE-Kennzeichnung
1994-12

Date of first CE-marking
1994-12

Gültig bis
2024-05-26

Valid until
2024-05-26

Effective

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Anlage I / Attachment I

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

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

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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

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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
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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
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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
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