Konformitätserklärung
Declaration of Conformity

Wir | We

B. Braun Melsungen AG
Carl-Braun-Str. 1
34212 Melsungen
Deutschland/Germany
SRN DE-MF-000000201

erklären in eigener Verantwortung, dass das Produkt

Sterifix® 0.2 µm
Injektionsfilter 0,2 µm zur Vermeidung partikulärer und mikrobieller Kontaminationen

Basis UDI-DI: 403923900000027426
(Artikelnummern siehe Anlage I)

mit den Anforderungen der Medizinprodukte Verordnung (EU) 2017/745 übereinstimmt

Konformitätsbewertungsverfahren
nach Anhang IX
der oben genannten Verordnung

Klassifizierung
gemäß Anhang VIII der oben genannten Verordnung
Klasse I steril

Benannte Stelle
TÜV SÜD Product Service GmbH
Kennnummer 0123

Gültig bis
gemäß gültigem EU Zertifikat
(G11 012974 0626)

hereby declare in our sole responsibility that the product

Sterifix® 0.2 µm
Injection filter 0.2 µm for avoidance of particulate and microbial contamination

Basic UDI-DI: 403923900000027426
(article numbers see attachment I)

is in conformity with the requirements of the Medical Device Regulation (EU) 2017/745

Conformity Assessment Procedure
according to annex IX
of the Regulation named above

Classification
according to annex VIII of the Regulation named above
Class I sterile

Notified Body
TÜV SÜD Product Service GmbH
Identification number 0123

Valid until
according to our valid EU Certificate
(G11 012974 0626)

Effective

Anlage I / Attachment I

Basic UDI-DI 403923900000027426

Art.-Nr. / Art. No.	**Produktname / Product name**	**Klasse / Class**
4099206	Sterifix® 0.2 µm	I steril / I sterile

Effective

Document amendment information

Version	Description of the changes
1.0	Initial Version under 2017/745 MDR based on change HC-CHC-M-DIV-2653

Effective

Title: Declaration of Conformity - 214-016-MDR - Sterifix 0.2 µm Initiator: Susanne ? Olbricht

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

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