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 die Produkte

hereby declare in our sole responsibility
that the products

Ecoflac® Connect
Überleitgerät für nichttoxische Flüssigkeiten in Einzeldosen mit Ecoflac® plus-Behälter. Geschlossenes System

Ecoflac® Connect
Transfer device for single dose, non-toxic fluids with Ecoflac® plus container. Closed System

Basis UDI-DI: 403923900000027324
(Artikelnummern siehe Anlage I)

Basic UDI-DI: 403923900000027324
(article numbers see attachment I)

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

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

Konformitätsbewertungsverfahren
nach Anhang IX
der oben genannten Verordnung

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

Klassifizierung
gemäß Anhang VIII der oben genannten Verordnung
Klasse I steril

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

Benannte Stelle
TÜV SÜD Product Service GmbH
Kennnummer 0123

Notified Body
TÜV SÜD Product Service GmbH
Identification number 0123

Gültig bis
gemäß gültigem EU Zertifikat
(G11 012974 0626)

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

Effective

Anlage I / Attachment I

Basic UDI-DI 403923900000027324

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
4090549	Ecoflac® Connect	I steril / I sterile
4090550	Ecoflac® Connect	I steril / I sterile
4090552	Ecoflac® Connect	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-2589

Effective

Title: Declaration of Conformity - 214-007-MDR - Ecoflac Connect Initiator: Susanne ? Olbricht

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

UserName: Olbricht, Susanne (olbrsude)
Title: HC-RA-DE08E Regulatory Affairs Manager IV-Systems
Date: Wednesday, 24 April 2024, 14:10 W. Europe Daylight Time
Meaning: Document signed as Author
==========

UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Wednesday, 24 April 2024, 17:43 W. Europe Daylight Time
Meaning: Approve Document
==========

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Wednesday, 24 April 2024, 21:23 W. Europe Daylight Time
Meaning: Approve Document
==========

Effective