

**Konformitätserklärung  
Declaration of Conformity**

Wir

**B. Braun Melsungen AG  
Carl-Braun-Straße 1  
34212 Melsungen  
Deutschland/Germany**

We

erklären in eigener Verantwortung,  
dass das/die Produkt/e**Easypump® II LT,  
Easypump® II ST**

Elastomere Infusionspumpen

(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 IIb**Benannte Stelle**  
TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 München  
Deutschland  
Kennnummer 0123**Datum der ersten CE-Kennzeichnung**  
2011-12-02**Gültig bis**  
2024-05-26hereby declare in our own responsibility  
that the product/s**Easypump® II LT,  
Easypump® II ST**

Elastomeric Infusion Pumps

(article numbers see attachment I)

is/are in compliance with the following  
directiveCouncil Directive 93/42/EEC of 14<sup>th</sup> June  
1993  
concerning Medical Devices  
amended by Directive 2007/47/EC**Conformity Assessment Procedure**  
nach Anhang II (ausgenommen Abschnitt 4)  
of the Council Directive named above**Classification**  
according to annex IX of the  
Council Directive named above  
Class IIb**Notified Body**  
TÜV SÜD Product Service GmbH  
Ridlerstraße 65  
80339 München  
Germany  
Identification number 0123**Date of first CE-marking**  
2011-12-02**Valid until**  
2024-05-26**Effective**

**Anlage I / Attachment I**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4540002	Easypump® II LT	IIb
4540003	Easypump® II LT	IIb
4540004	Easypump® II LT	IIb
4540006	Easypump® II LT	IIb
4540008	Easypump® II LT	IIb
4540010	Easypump® II LT	IIb
4540012	Easypump® II LT	IIb
4540014	Easypump® II LT	IIb
4540016	Easypump® II LT	IIb
4540018	Easypump® II LT	IIb
4540020	Easypump® II LT	IIb
4540022	Easypump® II LT	IIb
4540024	Easypump® II LT	IIb
4540026	Easypump® II LT	IIb
4540028	Easypump® II LT	IIb
4540030	Easypump® II LT	IIb
4540032	Easypump® II LT	IIb
4540034	Easypump® II LT	IIb
4540036	Easypump® II LT	IIb
4540038	Easypump® II LT	IIb
4540040	Easypump® II ST	IIb
4540042	Easypump® II ST	IIb
4540044	Easypump® II ST	IIb
4540046	Easypump® II ST	IIb
4540048	Easypump® II ST	IIb
4540050	Easypump® II ST	IIb
4540052	Easypump® II ST	IIb
4540054	Easypump® II ST	IIb
4540056	Easypump® II ST	IIb
4540058	Easypump® II ST	IIb

**Amendment Information**

<b>Version</b>	<b>Description of the changes</b>
08	During the review of the DoC as part of the change control HC-CHC-M-DIV-2007, it was found that non-CE article numbers 4540002-02, 4540004-02, 4540006-02, 4540008-02, 4540010-02, 4540012-02, 4540014-02, 4540016-02, 4540018-02, 4540020-02, 4540022-02, 4540024-02, 4540026-02, 4540028-02, 4540030-02, 4540032-02, 4540034-02, 4540036-02, 4540038-02, 4540040-02, 4540042-02, 4540044-02, 4540046-02, 4540048-02, 4540050-02, 4540052-02, 4540054-02, 4540056-02, 4540058-02 had been included by mistake (version 6). As these are not intended for the CE market, they must be removed
07	Update validity
06	Add new article codes 4540002-02, 4540004-02, 4540006-02, 4540008-02, 4540010-02, 4540012-02, 4540014-02, 4540016-02, 4540018-02, 4540020-02, 4540022-02, 4540024-02, 4540026-02, 4540028-02, 4540030-02, 4540032-02, 4540034-02, 4540036-02, 4540038-02, 4540040-02, 4540042-02, 4540044-02, 4540046-02, 4540048-02, 4540050-02, 4540052-02, 4540054-02, 4540056-02, 4540058-02
05	Correction of "Date of first CE-marking"
04	Add article code 4540003

Title: Declaration of Conformity - 197-001 - Easypump II ST/LT Initiator: Sandra ? Staufenberg

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

UserName: Staufenberg, Sandra (stausade)  
Title: Administrator Regulatory Affairs CoE Pain Control & CVC  
Date: Monday, 05 July 2021, 13:25 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, 05 July 2021, 16:42 W. Europe Daylight Time  
Meaning: Approve Document  
=====

UserName: Grosser, Simone (donnside)  
Title: Head of Regulatory Affairs CoE Pain Control & CVC  
Date: Tuesday, 06 July 2021, 06:54 W. Europe Daylight Time  
Meaning: Approve Document  
=====