

**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 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 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

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
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
4540022	Easypump® II LT	IIb
4540026	Easypump® II LT	IIb
4540028	Easypump® II LT	IIb
4540032	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

Version	Description of the changes
09	Deletion of article codes 4540020, 4540024, 4540030, 4540034, 4540036, 4540038 due to change control: HC-CHC-M-DIV-2043 Easypump II ST LT - Removal of Non-Released Articles from related documentation
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"

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:

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Meaning: Document signed as Author
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Meaning: Approve Document
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