

**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**  
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**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
4540002	Easypump® II LT	IIb
4540002-07	Easypump® II LT	IIb
4540002-20	Easypump® II LT	IIb
4540003	Easypump® II LT	IIb
4540003-07	Easypump® II LT	IIb
4540003-20	Easypump® II LT	IIb
4540004	Easypump® II LT	IIb
4540004-07	Easypump® II LT	IIb
4540004-20	Easypump® II LT	IIb
4540006	Easypump® II LT	IIb
4540006-07	Easypump® II LT	IIb
4540006-20	Easypump® II LT	IIb
4540008	Easypump® II LT	IIb
4540008-07	Easypump® II LT	IIb
4540008-20	Easypump® II LT	IIb
4540010	Easypump® II LT	IIb
4540010-07	Easypump® II LT	IIb
4540010-20	Easypump® II LT	IIb
4540012	Easypump® II LT	IIb
4540012-07	Easypump® II LT	IIb
4540012-20	Easypump® II LT	IIb
4540014	Easypump® II LT	IIb
4540014-07	Easypump® II LT	IIb
4540014-20	Easypump® II LT	IIb
4540016	Easypump® II LT	IIb
4540016-07	Easypump® II LT	IIb
4540016-20	Easypump® II LT	IIb
4540018	Easypump® II LT	IIb
4540018-07	Easypump® II LT	IIb
4540018-20	Easypump® II LT	IIb
4540022	Easypump® II LT	IIb
4540022-07	Easypump® II LT	IIb
4540022-20	Easypump® II LT	IIb
4540026	Easypump® II LT	IIb
4540026-07	Easypump® II LT	IIb
4540026-20	Easypump® II LT	IIb
4540028	Easypump® II LT	IIb
4540028-07	Easypump® II LT	IIb
4540028-20	Easypump® II LT	IIb
4540032	Easypump® II LT	IIb
4540032-07	Easypump® II LT	IIb
4540032-20	Easypump® II LT	IIb
4540040	Easypump® II ST	IIb
4540040-07	Easypump® II ST	IIb
4540040-20	Easypump® II ST	IIb

4540042	Easypump® II ST	IIb
4540042-07	Easypump® II ST	IIb
4540042-20	Easypump® II ST	IIb
4540044	Easypump® II ST	IIb
4540044-07	Easypump® II ST	IIb
4540044-20	Easypump® II ST	IIb
4540046	Easypump® II ST	IIb
4540046-07	Easypump® II ST	IIb
4540046-20	Easypump® II ST	IIb
4540048	Easypump® II ST	IIb
4540048-07	Easypump® II ST	IIb
4540048-20	Easypump® II ST	IIb
4540050	Easypump® II ST	IIb
4540050-07	Easypump® II ST	IIb
4540050-20	Easypump® II ST	IIb
4540052	Easypump® II ST	IIb
4540052-07	Easypump® II ST	IIb
4540052-20	Easypump® II ST	IIb
4540054	Easypump® II ST	IIb
4540054-07	Easypump® II ST	IIb
4540054-20	Easypump® II ST	IIb
4540056	Easypump® II ST	IIb
4540056-07	Easypump® II ST	IIb
4540056-20	Easypump® II ST	IIb
4540058	Easypump® II ST	IIb
4540058-07	Easypump® II ST	IIb
4540058-20	Easypump® II ST	IIb

**Amendment Information**

<b>Version</b>	<b>Description of the changes</b>
10	Add new article codes 4540002-07, 4540002-20, 4540003-07, 4540003-20, 4540004-07, 4540004-20, 4540006-07, 4540006-20, 4540008-07, 4540008-20, 4540010-07, 4540010-20, 4540012-07, 4540012-20, 4540014-07, 4540012-20, 4540014-07, 4540014-20, 4540016-07, 4540016-20, 4540018-07, 4540018-20, 4540022-07, 4540022-20, 4540026-07, 4540026-20, 4540028-07, 4540028-20, 4540032-07, 4540032-20, 4540040-07, 4540040-20, 4540042-07, 4540042-20, 4540044-07, 4540044-20, 4540046-07, 4540046-20, 4540048-07, 4540048-20, 4540050-07, 4540050-20, 4540052-07, 4540052-20, 4540054-07, 4540054-20, 4540056-07, 4540056-20, 4540058-07, 4540058-20 due to change control HC-CHC-M-DIV-1960 Easypump II ST LT – Regional Label Concept
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

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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