Konformitätserklärung
Declaration of Conformity

Wir	We

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

erklären in eigener Verantwortung, dass das/die Produkt/e	hereby declare in our own responsibility that the product/s
Solofix® Safety Universal **Solofix® Safety Fine** **Solofix® Safety Neonat** Lanzette, Blut, steril	**Solofix® Safety Universal** **Solofix® Safety Fine** **Solofix® Safety Neonat** Lancets, blood, sterile
(Artikelnummern siehe Anlage I)	(article numbers see attachment I)
mit den Anforderungen der folgenden Richtlinie übereinstimmt/übereinstimmen	is/are in compliance with the following directive
Richtlinie 93/42/EWG des Rates vom 14. Juni 1993 über Medizinprodukte, geändert durch Richtlinie 2007/47/EG	Council Directive 93/42/EEC of 14 June 1993 concerning Medical Devices, amended by Directive 2007/47/EG
Konformitätsbewertungsverfahren nach Anhang II ohne Abschnitt 4 der oben genannten Richtlinie	**Conformity assessment procedure** according to annex II without part 4 of the Directive named above
Klassifizierung gemäß Anhang IX der oben genannten Richtlinie: Klasse IIa	**Classification** according to annex IX of the Directive named above: Class IIa
Benannte Stelle TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München Deutschland Kennnummer 0123	**Notified body** TÜV SÜD Product Service GmbH Ridlerstraße 65 80339 München Germany Identification number 0123
Datum der ersten CE-Kennzeichnung 2008-05	**Date of first CE-marking** 2008-05
Gültig bis 2024-05-26	**Valid until** 2024-05-26

Effective

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product Name	Klasse / Class
6183000	Solofix® Safety Universal	IIa
6183010	Solofix® Safety Fine	IIa
6183020	Solofix® Safety Neonat	IIa

Amendment Information

Version	Description of the changes
09	Yearly revision acc. to TÜV audit 05-2009 Version 1: BBMAG OPM; Version 2: BBMAG
10	Adaption to SOP HO-DDDD-M-5-2-05-715 Add art. no 6183040, 60183050 again (SAP status M4/V4 30.06.2014 and 17.09.2012, articles have not expired yet)
11	Adaption of conformity assessment procedure to “according to annex II without part 4”
12	Delete Out of Market art. no. 6183040, 6183050
13	Adaptation of validity to the MDR-deadline

Title: Declaration of Conformity - 084-005 - Solofix Safety Initiator: Anna Heil

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

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