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

Omnican® 20
Omnican® 40
Omnican® 50
Omnican® 100
Omnifix® 40 Duo
Omnifix® 40 Solo
Omnifix® 100 Duo
Omnifix® 100 Solo
Injekt® 40 Solo
Injekt® 40 Duo

Spritze, Insulin, steril
(Artikelnummern siehe Anlage I)

Syringes, Insulin, sterile
(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

Effective

Datum der ersten CE-Kennzeichnung
1997-08

Gültig bis
2024-05-26

Date of first CE-marking
1997-08

Valid until
2024-05-26

Effective

Anlage I / Attachment I

Art.-Nr. / Art. No.	Produktname / Product Name	Klasse / Class
9161619	Omnican® 20	IIa
9161619S	Omnican® 20	IIa
9161627	Omnican® 40	IIa
9161627S	Omnican® 40	IIa
9161635	Omnican® 40	IIa
9161635S	Omnican® 40	IIa
9161627SC	Omnican® 40	IIa
9161635SCN	Omnican® 40	IIa
9151125	Omnican® 50	IIa
9151125S	Omnican® 50	IIa
9151117	Omnican® 50	IIa
9151117S	Omnican® 50	IIa
9151141	Omnican® 100	IIa
9151141S	Omnican® 100	IIa
9151133	Omnican® 100	IIa
9151133S	Omnican® 100	IIa
9151141SC	Omnican® 100	IIa
9151133SCN	Omnican® 100	IIa
9161333C	Omnifix® 40 Duo	IIa
9161333V	Omnifix® 40 Duo	IIa
9161309V	Omnifix® 40 Solo	IIa
9161376V	Omnifix® 100 Duo	IIa
9161376C	Omnifix® 100 Duo	IIa
9161708V	Omnifix® 100 Solo	IIa
9166432V	Injekt® 40 Duo	IIa
9166432C	Injekt® 40 Duo	IIa
9166408V	Injekt® 40 Solo	IIa

Amendment Information

Version	Description of the changes
28	Adaption to SOP HO-DDDD-M-5-2-05-715
29	Adaption of conformity assessment procedure to “according to annex II without part 4”
30	Add art. no. 9161333C
31	Add art. no. 9161635SCN, 9151133SCN
32	No content change. Editorial change: Sorting the article list by product groups

Title: Declaration of Conformity - 020-001(a) - Omnican, Omnifix, Injekt 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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