

**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**Haselmeier®,
Omnican® fine,
Omnican® fine Comfort**
Penkanüle, steril
(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
ohne Abschnitt 4
der oben genannten Richtlinie**Klassifizierung**
gemäß Anhang IX der oben genannten
Richtlinie:
Klasse IIa**Benannte Stelle**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Deutschland
Kennnummer 0123**Datum der ersten CE-Kennzeichnung**
2004-02**Gültig bis**
2024-05-26hereby declare in our own responsibility
that the product/s**Haselmeier®,
Omnican® fine,
Omnican® fine Comfort**
Pen needle, sterile
(article numbers see attachment I)

is/are in compliance with the following directive

Council Directive 93/42/EEC of 14 June 1993
concerning Medical Devices,
amended by Directive 2007/47/EG**Conformity assessment procedure**
according to annex II
without part 4
of the Directive named above**Classification**
according to annex IX of the Directive named
above:
Class IIa**Notified body**
TÜV SÜD Product Service GmbH
Ridlerstraße 65
80339 München
Germany
Identification number 0123**Date of first CE-marking**
2004-02**Valid until**
2024-05-26

Art.-Nr. / Art. No.	Produktname / Product Name	Klasse / Class
4592158	Haselmeier®	Ila
9166700SB	Omnican® fine	Ila
9166718SB	Omnican® fine	Ila
9166726SB	Omnican® fine	Ila
9166742SB	Omnican® fine	Ila
9166750SB	Omnican® fine	Ila
9166769SB	Omnican® fine	Ila
9167625SE	Omnican® fine Comfort	Ila
9167625WE	Omnican® fine	Ila
9167641ES	Omnican® fine Comfort	Ila
9167641SE	Omnican® fine Comfort	Ila
9167641WE	Omnican® fine	Ila
9167650WE	Omnican® fine	Ila
9167668	Omnican® fine	Ila
9167668ES	Omnican® fine Comfort	Ila
9167668SE	Omnican® fine Comfort	Ila
9167668WE	Omnican® fine	Ila
9167684	Omnican® fine	Ila
9167684ES	Omnican® fine Comfort	Ila
9167684SE	Omnican® fine Comfort	Ila
9167684WE	Omnican® fine	Ila
9167811DE	Omnican® fine	Ila
9167811EX	Omnican® fine	Ila
9167811WE	Omnican® fine	Ila
9167820WE	Omnican® fine	Ila
9167846SE	Omnican® fine Comfort	Ila
9167889	Omnican® fine	Ila
9168934DE	Omnican® fine	Ila
9168934EX	Omnican® fine	Ila
9168956	Omnican® fine	Ila
9168956DE	Omnican® fine	Ila
9168956EX	Omnican® fine	Ila
9168956WE	Omnican® fine	Ila
9168978	Omnican® fine	Ila
9168978DE	Omnican® fine	Ila
9168978EX	Omnican® fine	Ila
9168978WE	Omnican® fine	Ila
9168982	Omnican® fine	Ila
9168982D	Omnican® fine	Ila
9168982EX	Omnican® fine	Ila
9168990	Omnican® fine	Ila
9168990D	Omnican® fine	Ila
9168990DE	Omnican® fine	Ila
9168990EX	Omnican® fine	Ila
9168990WE	Omnican® fine	Ila
929G12S-03	Omnican® fine	Ila

929G12S-20	Omnican® fine	Ila
929G12S-41	Omnican® fine	Ila
929G12S-43	Omnican® fine	Ila
929G12S-44	Omnican® fine	Ila
929G12S-AP	Omnican® fine	Ila
931G04S-03	Omnican® fine	Ila
931G04S-20	Omnican® fine	Ila
931G04S-41	Omnican® fine	Ila
931G04S-43	Omnican® fine	Ila
931G04S-44	Omnican® fine	Ila
931G04S-AP	Omnican® fine	Ila
931G04SCN	Omnican® fine	Ila
931G04SCN1	Omnican® fine	Ila
931G06S-03	Omnican® fine	Ila
931G06S-20	Omnican® fine	Ila
931G06S-41	Omnican® fine	Ila
931G06S-43	Omnican® fine	Ila
931G06S-44	Omnican® fine	Ila
931G06S-AP	Omnican® fine	Ila
931G06SCN	Omnican® fine	Ila
931G06SCN1	Omnican® fine	Ila
931G08S-03	Omnican® fine	Ila
931G08S-20	Omnican® fine	Ila
931G08S-41	Omnican® fine	Ila
931G08S-43	Omnican® fine	Ila
931G08S-44	Omnican® fine	Ila
931G08S-AP	Omnican® fine	Ila
932G04-41	Omnican® fine	Ila
932G04S-03	Omnican® fine	Ila
932G04S-04	Omnican® fine	Ila
932G04S-41	Omnican® fine	Ila
932G04S-43	Omnican® fine	Ila
932G04S-AP	Omnican® fine	Ila
932G04SCN	Omnican® fine	Ila
932G04SCN1	Omnican® fine	Ila
932G05-41	Omnican® fine	Ila
932G05S-AP	Omnican® fine	Ila
932G05SCN	Omnican® fine	Ila
932G05SCN1	Omnican® fine	Ila
932G06-41	Omnican® fine	Ila
932G06S-03	Omnican® fine	Ila
932G06S-04	Omnican® fine	Ila
932G06S-41	Omnican® fine	Ila
932G06S-43	Omnican® fine	Ila
932G06S-AP	Omnican® fine	Ila
932G06SCN	Omnican® fine	Ila
932G06SCN1	Omnican® fine	Ila

932P04	Omnican® fine	Ila
932P05	Omnican® fine	Ila
932P06	Omnican® fine	Ila

Amendment Information

Version	Description of changes
56.0	Change of amendment information to English
57.0	Add art. no. 932G04SCN, 932G05SCN, 932G06SCN, 932G04SCN1, 932G05SCN1, 932G06SCN1
58.0	Add art. no. 931G04SCN1 and 931G06SCN1
59.0	Add art. no. 932P04, 932P05, 932P06 formerly covered by DoC 020-024
60.0	Removal of Art. No. 929G12S-02, 931G04S-02, 931G06S-02, 931G08S-02, 932G04S-02, 932G06S-02 due to not being CE-marked

Title: Declaration of Conformity - 020-020 - Omnican fine Initiator: Marie Fischer

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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Date: Tuesday, 08 August 2023, 10:20 W. Europe Daylight Time
Meaning: Approve Document
