

**Konformitätserklärung  
Declaration of Conformity**

Wir

We

**B. Braun Melsungen AG  
Carl-Braun-Str. 1  
34212 Melsungen  
Deutschland/Germany  
SRN DE-MF-000000201**erklären in eigener Verantwortung,  
dass das Produkt**Omnican® fine,**

Pen needle, steril

(Artikelnummern und Basic UDI-DI siehe Anlage I)

mit den Anforderungen der Medizinprodukte  
Verordnung (EU) 2017/745  
übereinstimmt/übereinstimmen**Konformitätsbewertungsverfahren  
nach Anhang IX****Klassifizierung**gemäß Anhang VIII der oben genannten  
Verordnung  
Klasse IIa**Benannte Stelle**TÜV SÜD Product Service GmbH  
Kennnummer 0123**Gültig bis**gemäß gültigem EC Zertifikat  
(Nr. G10 012974 0611)hereby declare in our own responsibility  
that the product**Omnican® fine,**

Pen needle, sterile

(article numbers and Basic UDI-DI see attachment I)

is in conformity with the requirements of the  
Medical Device Regulation (EU) 2017/745**Conformity Assessment Procedure  
according to annex IX****Classification**according to annex VIII of the Regulation named  
above  
Class IIa**Notified Body**TÜV SÜD Product Service GmbH  
Identification number 0123**Valid until**according to our valid EC Certificate  
(No. G10 012974 0611)

**Anlage I / Attachment I****Basic UDI-DI 4039239000001006ZF**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
9167641WE	Omnican® fine	Ila
9167650WE	Omnican® fine	Ila
9167668WE	Omnican® fine	Ila
9167684WE	Omnican® fine	Ila
9167820WE	Omnican® fine	Ila
929G12S-03	Omnican® fine	Ila
929G12S-41	Omnican® fine	Ila
929G12S-43	Omnican® fine	Ila
931G04S-03	Omnican® fine	Ila
931G04S-41	Omnican® fine	Ila
931G04S-43	Omnican® fine	Ila
931G04SCN	Omnican® fine	Ila
931G04SCN1	Omnican® fine	Ila
931G06S-03	Omnican® fine	Ila
931G06S-41	Omnican® fine	Ila
931G06S-43	Omnican® fine	Ila
931G06S-AP	Omnican® fine	Ila
931G06SCN	Omnican® fine	Ila
931G06SCN1	Omnican® fine	Ila
931G08S-03	Omnican® fine	Ila
931G08S-41	Omnican® fine	Ila
931G08S-43	Omnican® fine	Ila
931G08S-44	Omnican® fine	Ila
932G04S-03	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
932G05SCN	Omnican® fine	Ila
932G05SCN1	Omnican® fine	Ila
932G06S-03	Omnican® fine	Ila
932G06S-41	Omnican® fine	Ila
932G06S-43	Omnican® fine	Ila
932G06SCN	Omnican® fine	Ila
932G06SCN1	Omnican® fine	Ila
932P04	Omnican® fine	Ila
932P05	Omnican® fine	Ila
932P06	Omnican® fine	Ila

### Document amendment information

Version	Description of the changes
1.0	Initial Version of Declaration of Conformity according to Medical Device Regulation (MDR) 2017/745

Title: Declaration of Conformity 260-001 - Omnican fine pen needle - MDR Initiator: Ulrich ? Jedelhauser

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

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Meaning: Approve Document

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