

**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 die Produkte**Omnican® 20
Omnican® 40
Omnican® 50
Omnican® 100**3-piece Single-use Insulin syringe
with integrated needleBasis UDI-DI: 4039239000009362Z
(Artikelnummern siehe Anlage I)**Omnican® F
IBSA FSH/LH**3-piece Single-use fine dosage syringe
with integrated needleBasis UDI-DI: 40392390000093937
(Artikelnummern siehe Anlage I)mit den Anforderungen der Medizinprodukte
Verordnung (EU) 2017/745 übereinstimmen**Konformitätsbewertungsverfahren
nach Anhang IX
Verordnung****Klassifizierung**
gemäß Anhang VIII der oben genannten
Verordnung
Klasse IIa**Benannte Stelle**
TÜV SÜD Product Service GmbH
Kennnummer 0123**Gültig bis**
gemäß gültigem EU Zertifikat
(Nr. G10 012974 0611)hereby declare in our own responsibility
that the products**Omnican® 20
Omnican® 40
Omnican® 50
Omnican® 100**3-piece Single-use Insulin syringe
with integrated needleBasic UDI-DI: 4039239000009362Z
(article numbers see attachment I)**Omnican® F
IBSA FSH/LH**3-piece Single-use fine dosage syringe
with integrated needleBasis UDI-DI: 40392390000093937
(article numbers see attachment I)are in conformity with the requirements of the
Medical Device Regulation (EU) 2017/745**Conformity Assessment Procedure**
according to annex IX
of the Regulation named above**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 EU Certificate
(No. G10 012974 0611)

Anlage I / Attachment I**Basic UDI-DI 4039239000009362Z**

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
9151117S	Omnican® 50	Ila
9151125S	Omnican® 50	Ila
9151133S	Omnican® 100	Ila
9151141S	Omnican® 100	Ila
9151141SC	Omnican® 100	Ila
9161619S	Omnican® 20	Ila
9161627S	Omnican® 40	Ila
9161627SC	Omnican® 40	Ila
9161635S	Omnican® 40	Ila

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Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
9161502S	Omnican® F	Ila
9161530S	IBSA FSH/LH	Ila

Document amendment information

Version	Description of the changes
1.0	Initial Version under Medical Device Regulation (EU) 2017/745.

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

UserName: Manschwetus, Jascha (mansjsde)
Title: Junior Manager Regulatory Affairs | CoE Infusion & Pain Therapy
Date: Thursday, 16 May 2024, 12:49 W. Europe Daylight Time
Meaning: Document signed as Author

UserName: Seidel, Stefan (seidstde)
Title: Head of Regulatory Affairs CoE Infusion & Pain Therapy
Date: Thursday, 16 May 2024, 15:08 W. Europe Daylight Time
Meaning: Approve Document

UserName: Brand, Thomas (brantode)
Title: HC-QM-DE08 Vice President QM for non-active Medical Devices
Date: Thursday, 16 May 2024, 20:17 W. Europe Daylight Time
Meaning: Approve Document
