

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/die Produkt/e

Introcan Safety[®],
Introcan Safety[®]-W
Venenverweilkanülen

(Artikelnummern und Basic UDI-DI siehe Anlage I)

mit den Anforderungen der Medizinprodukte
Verordnung (EU) 2017/745
übereinstimmt/übereinstimmen

Konformitätsbewertungsverfahren
nach Anhang IX
der oben genannten 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 product/s

Introcan Safety[®],
Introcan Safety[®]-W
I. V. cannulae

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

is/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: 40392390000007632S

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
---	IntrocanSafety® Winged (PUR – European label -01)	---
4253523-01	Introcan Safety®-W	Ila
4251614-01	Introcan Safety®-W	Ila
4253540-01	Introcan Safety®-W	Ila
4253574-01	Introcan Safety®-W	Ila
4253566-01	Introcan Safety®-W	Ila
4253604-01	Introcan Safety®-W	Ila
4253590-01	Introcan Safety®-W	Ila
4253612-01	Introcan Safety®-W	Ila
4253639-01	Introcan Safety®-W	Ila
---	Introcan Safety® Wingless (PUR – European label - 01)	---
4251601-01	Introcan Safety®	Ila
4251623-01	Introcan Safety®	Ila
4251607-01	Introcan Safety®	Ila
4251628-01	Introcan Safety®	Ila
4251622-01	Introcan Safety®	Ila
4251652-01	Introcan Safety®	Ila
4251644-01	Introcan Safety®	Ila
4251621-01	Introcan Safety®	Ila
4251687-01	Introcan Safety®	Ila
4251679-01	Introcan Safety®	Ila
4251620-01	Introcan Safety®	Ila
4251709-01	Introcan Safety®	Ila
4251695-01	Introcan Safety®	Ila
4251717-01	Introcan Safety®	Ila

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
---	Introcan Safety® Winged (FEP– European label - 01)	---
4254503-01	Introcan Safety®-W	Ila
4254511-01	Introcan Safety®-W	Ila
4254546-01	Introcan Safety®-W	Ila
4254538-01	Introcan Safety®-W	Ila
4254562-01	Introcan Safety®-W	Ila
4254554-01	Introcan Safety®-W	Ila
4254570-01	Introcan Safety®-W	Ila
4254597-01	Introcan Safety®-W	Ila
---	Introcan Safety® Wingless (FEP – European label - 01)	---
4252500-01	Introcan Safety®	Ila
4252519-01	Introcan Safety®	Ila
4252520-01	Introcan Safety®	Ila
4252543-01	Introcan Safety®	Ila
4252535-01	Introcan Safety®	Ila
4252527-01	Introcan Safety®	Ila
4252560-01	Introcan Safety®	Ila
4252551-01	Introcan Safety®	Ila
4252586-01	Introcan Safety®	Ila
4252578-01	Introcan Safety®	Ila
4251890-01	Introcan Safety®	Ila
4252594-01	Introcan Safety®	Ila

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
---	Introcan Safety® Winged (PUR – AP label - 03)	---
4251614-03	Introcan Safety®-W	Ila
4253523-03	Introcan Safety®-W	Ila
4253540-03	Introcan Safety®-W	Ila
4253574-03	Introcan Safety®-W	Ila
4253566-03	Introcan Safety®-W	Ila
4253604-03	Introcan Safety®-W	Ila
4253590-03	Introcan Safety®-W	Ila
4253612-03	Introcan Safety®-W	Ila
4253639-03	Introcan Safety®-W	Ila
--	Introcan Safety® Wingless (PUR – AP label -03)	--
4251607-03	Introcan Safety®	Ila
4251601-03	Introcan Safety®	Ila
4251628-03	Introcan Safety®	Ila
4251652-03	Introcan Safety®	Ila
4251644-03	Introcan Safety®	Ila
4251687-03	Introcan Safety®	Ila
4251679-03	Introcan Safety®	Ila
4251709-03	Introcan Safety®	Ila
4251695-03	Introcan Safety®	Ila
4251717-03	Introcan Safety®	Ila

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
--	Introcan Safety®-Winged (FEP – AP label - 03)	--
4254503-03	Introcan Safety®-W	Ila
4254511-03	Introcan Safety®-W	Ila
4254546-03	Introcan Safety®-W	Ila
4254538-03	Introcan Safety®-W	Ila
4254562-03	Introcan Safety®-W	Ila
4254554-03	Introcan Safety®-W	Ila
4254570-03	Introcan Safety®-W	Ila
4254597-03	Introcan Safety®-W	Ila
--	Introcan Safety® Wingless (FEP – AP label - 03)	--
4252500-03	Introcan Safety®	Ila
4252519-03	Introcan Safety®	Ila
4252535-03	Introcan Safety®	Ila
4252527-03	Introcan Safety®	Ila
4252560-03	Introcan Safety®	Ila
4252551-03	Introcan Safety®	Ila
4252586-03	Introcan Safety®	Ila
4252578-03	Introcan Safety®	Ila
4251890-03	Introcan Safety®	Ila
4252594-03	Introcan Safety®	Ila

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
--	Introcan Safety® Winged (PUR – SA label -04)	--
4251614-04	Introcan Safety®-W	Ila
4253523-04	Introcan Safety®-W	Ila
4253540-04	Introcan Safety®-W	Ila
4253574-04	Introcan Safety®-W	Ila
4253566-04	Introcan Safety®-W	Ila
4253604-04	Introcan Safety®-W	Ila
4253590-04	Introcan Safety®-W	Ila
4253612-04	Introcan Safety®-W	Ila
4253639-04	Introcan Safety®-W	Ila
--	Introcan Safety® Wingless (PUR – SA label - 04)	--
4251607-04	Introcan Safety®	Ila
4251601-04	Introcan Safety®	Ila
4251628-04	Introcan Safety®	Ila
4251652-04	Introcan Safety®	Ila
4251644-04	Introcan Safety®	Ila
4251687-04	Introcan Safety®	Ila
4251679-04	Introcan Safety®	Ila
4251709-04	Introcan Safety®	Ila
4251695-04	Introcan Safety®	Ila
4251717-04	Introcan Safety®	Ila
--	Introcan Safety® Winged (FEP – SA label - 04)	--
4254503-04	Introcan Safety®-W	Ila
4254511-04	Introcan Safety®-W	Ila
4254538-04	Introcan Safety®-W	Ila
4254562-04	Introcan Safety®-W	Ila
4254554-04	Introcan Safety®-W	Ila
4254570-04	Introcan Safety®-W	Ila
4254597-04	Introcan Safety®-W	Ila
--	Introcan Safety® Wingless (FEP – SA label - 04)	--
4252500-04	Introcan Safety®	Ila
4252519-04	Introcan Safety®	Ila
4252535-04	Introcan Safety®	Ila
4252560-04	Introcan Safety®	Ila
4252551-04	Introcan Safety®	Ila
4252586-04	Introcan Safety®	Ila
4252578-04	Introcan Safety®	Ila
4251890-04	Introcan Safety®	Ila
4252594-04	Introcan Safety®	Ila

Art.-Nr. / Art. No.	Produktname / Product name	Klasse / Class
--	Introcan Safety® Wingless (PUR-JP label - JP)	--
4251601JP	Introcan Safety®	Ila
4251607JP	Introcan Safety®	Ila
4251628JP	Introcan Safety®	Ila
4251644JP	Introcan Safety®	Ila
4251652JP	Introcan Safety®	Ila
4251679JP	Introcan Safety®	Ila
4251687JP	Introcan Safety®	Ila
4251695JP	Introcan Safety®	Ila
4251709JP	Introcan Safety®	Ila
--	Introcan Safety® Winged (PUR-JP label-JP)	--
4251614JP	Introcan Safety®-W	Ila
4253523JP	Introcan Safety®-W	Ila
4253540JP	Introcan Safety®-W	Ila
4253566JP	Introcan Safety®-W	Ila
4253574JP	Introcan Safety®-W	Ila
4253604JP	Introcan Safety®-W	Ila

Document amendment information

Version	Description of the changes
1.0	Initial Version

Title: Declaration of Conformity 120-010 - Introcan Safety - MDR Initiator: Ulrich ? Jedelhauser

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

UserName: Jedelhauser, Ulrich (jedeulde)
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Date: Friday, 03 May 2024, 15:08 W. Europe Daylight Time
Meaning: Document signed as Author
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UserName: Seidel, Stefan (seidstde)
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