

## 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<sup>®</sup>,**  
**Introcan Safety<sup>®</sup>-W**  
Venenerweilkanülen

(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<sup>®</sup>,**  
**Introcan Safety<sup>®</sup>-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: 4039239000007632S**

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
---	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

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
---	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

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
---	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

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
--	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

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
--	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

<b>Art.-Nr. / Art. No.</b>	<b>Produktname / Product name</b>	<b>Klasse / Class</b>
--	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:

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