

TITLE: Declaration of Conformity for BD Venflon™ Pro Safety and BD Venflon™ Pro Instaflash technology

EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Becton Dickinson Infusion Therapy AB Florettgatan 29C, PO Box 631 SE-251 06 Helsingborg, Sweden
Manufacturing Site(s):	Becton Dickinson Medical (S) Pte Ltd. 30 Tuas Avenue 2, Singapore 639461 Singapore
Products:	<p>BD Venflon™ Pro Safety I.V. Cannula</p> <ul style="list-style-type: none"> ▪ 393222 22GA BD Venflon Pro Safety ▪ 393224 20GA BD Venflon Pro Safety ▪ 393226 18GA BD Venflon Pro Safety ▪ 393227 18GA BD Venflon Pro Safety ▪ 393228 17GA BD Venflon Pro Safety ▪ 393229 16GA BD Venflon Pro Safety ▪ 393230 14GA BD Venflon Pro Safety ▪ 393242 22GA BD Venflon Pro Safety-INDIA ▪ 393244 20GA BD Venflon Pro Safety-INDIA ▪ 393246 18GA BD Venflon Pro Safety-INDIA ▪ 393247 18GA BD Venflon Pro Safety-INDIA ▪ 393248 17GA BD Venflon Pro Safety-INDIA ▪ 393249 16GA BD Venflon Pro Safety-INDIA ▪ 393250 14GA BD Venflon Pro Safety-INDIA <p>BD Venflon™ Pro Safety I.V. Cannula with Instaflash™ Needle Technology</p> <ul style="list-style-type: none"> ▪ 393280 22GA BD Venflon Pro Safety I.V. Cannula with INSTAFLASH ▪ 393281 20GA BD Venflon Pro Safety I.V. Cannula with INSTAFLASH ▪ 393282 18GA BD Venflon Pro Safety I.V. Cannula with INSTAFLASH ▪ 393283 18GA BD Venflon Pro Safety I.V. Cannula with INSTAFLASH ▪ 393284 22GA BD Venflon Pro Safety I.V. Cannula with INSTAFLASH-INDIA ▪ 393285 20GA BD Venflon Pro Safety I.V. Cannula with INSTAFLASH-INDIA ▪ 393286 18GA BD Venflon Pro Safety I.V. Cannula with INSTAFLASH-INDIA ▪ 393287 18GA BD Venflon Pro Safety I.V. Cannula with INSTAFLASH-INDIA
Classification:	Class IIa, Annex IX, Rule 7
Conformity Assessment Route:	Annex II, section 3.2
GMDN:	<ul style="list-style-type: none"> ▪ GMDN Code: 64574 ▪ GMDN Term: Peripheral intravenous cannula

We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. All supporting documentation is retained at the premises of the manufacturer.

Harmonised Standards:	EN ISO 13485:2016 EN ISO 14971:2012
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	<p>EN 20594-1:1993 EN ISO 10555-1:2009 EN ISO 10993-1:2009 EN ISO 11607-1:2009 EN ISO 11607-2:2006 EN 556-1:2001 EN ISO 11137-1:2006 EN ISO 11137-2:2013 EN ISO 11737-1:2006 EN ISO 11737-2:2009 EN 1041:2008 EN ISO 11135-1:2014</p>
Non-Harmonised Standards:	<p>ISO 594-2:1998 ISO 15223-1:2016 ISO 14644-1:1999 ISO 9626:1991 ISO 10555-1:2013 ISO 10555-5:2013 ISO 23908:2011</p>
Notified Body:	<p>BSI Group, The Netherlands B.V. Say Buidling, John M. Keynesplein 9 Amsterdam 1066 EP Netherlands Notified Body ID Number: 2797</p>
CE Certificate Number:	CE 597884
Date of issuance of original CE certificate:	11 January 1996

Date: 4th May 2020



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<u>REVISION HISTORY</u>		
Current Version Prepared By: Heather Hagvik		
REV.	Revision Description	Releasing ECO (if applicable)
A	Initial Release, New DoC added Venflon Pro Safety and Venflon Pro Safety with Instaflash technology into one DoC. Harominsed standards were updated to reflect up to date information.	NA
B	Updated new notified body number	N/A
C	Added signature	N/A
D	Removed Obsoleted German SKUs	N/A
E	Added new GMDN Code	N/A

[Do not include revision history page in page numbering.](#)