

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 India Pvt. Ltd. Plot No. 1, Sector 3, IMT, Bawal-123 501, District Rewari, Haryana, India
Products:	BD Venflon™ Pro I.V. Cannula <ul style="list-style-type: none">▪ 393202 22GA BD Venflon Pro I.V. Cannula▪ 393204 20GA BD Venflon Pro I.V. Cannula▪ 393206 18GA BD Venflon Pro I.V. Cannula▪ 393207 18GA BD Venflon Pro I.V. Cannula▪ 393208 17GA BD Venflon Pro I.V. Cannula▪ 393209 16GA BD Venflon Pro I.V. Cannula▪ 393210 14GA BD Venflon Pro I.V. Cannula▪ 393232 22GA BD Venflon Pro I.V. Cannula - INDIA▪ 393234 20GA BD Venflon Pro I.V. Cannula - INDIA▪ 393236 18GA BD Venflon Pro I.V. Cannula - INDIA▪ 393237 18GA BD Venflon Pro I.V. Cannula - INDIA▪ 393238 17GA BD Venflon Pro I.V. Cannula - INDIA▪ 393239 16GA BD Venflon Pro I.V. Cannula - INDIA▪ 393240 14GA BD Venflon Pro I.V. Cannula - INDIA▪ 393252 22GA BD Venflon Pro I.V. Cannula▪ 393254 20GA BD Venflon Pro I.V. Cannula▪ 393256 18GA BD Venflon Pro I.V. Cannula
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 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
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	EN ISO 11137-2:2013 EN ISO 11737-1:2006 EN ISO 11737-2:2009 EN ISO 15223-1:2016 EN 1041:2008 EN ISO 11135-1:2014
Non-Harmonised Standards:	ISO 594-2:1998 ISO 14644-1:1999 ISO 9626:1991 ISO 10555-1:2013 ISO 10555-5:2013
Notified Body:	BSI Group, The Netherlands B.V. Say Buidling, John M. Keynesplein 9 Amsterdam 1066 EP Netherlands Notified Body ID Number: 2797
CE Certificate Number:	CE 597884
Date of issuance of original CE certificate:	11 January 1996

Date: 4th May 2020



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Becton Dickinson Infusion Therapy AB

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TITLE: Declaration of Conformity for BD Venflon™ Pro Products**REVISION HISTORY**

Current Version Prepared By: Heather Hagvik

REV.	Revision Description	Releasing ECO (if applicable)
A	Initial Release, New DoC into SAP. Updated new Notified body number.	NA
B	Added signature	N/A
C	Added India as a new manufacturing site	N/A
D	Removed Singapore as manufacturing site and updated India's address	N/A
E	Added new GMDN code	N/A

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