# EC DECLARATION OF CONFORMITY

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| **Legal Manufacturer:** | Becton Dickinson Infusion Therapy AB<br>Florettgatan 29C, PO Box 631<br>SE-251 06 Helsingborg, Sweden |
| **Manufacturing Site(s):** | Becton Dickinson Medical (S) Pte Ltd.<br>30 Tuas Avenue 2, Singapore<br>639461 Singapore |
| **Products:** | **BD Venflon™ Pro Safety I.V. Cannula**<br>▪ 393222 22GA BD Venflon Pro Safety<br>▪ 393224 20GA BD Venflon Pro Safety<br>▪ 393226 18GA BD Venflon Pro Safety<br>▪ 393227 18GA BD Venflon Pro Safety<br>▪ 393228 17GA BD Venflon Pro Safety<br>▪ 393229 16GA BD Venflon Pro Safety<br>▪ 393230 14GA BD Venflon Pro Safety<br>▪ 393242 22GA BD Venflon Pro Safety-INDIA<br>▪ 393244 20GA BD Venflon Pro Safety-INDIA<br>▪ 393246 18GA BD Venflon Pro Safety-INDIA<br>▪ 393247 18GA BD Venflon Pro Safety-INDIA<br>▪ 393248 17GA BD Venflon Pro Safety-INDIA<br>▪ 393249 16GA BD Venflon Pro Safety-INDIA<br>▪ 393250 14GA BD Venflon Pro Safety-INDIA<br>▪ 393262 22GA BD Venflon Pro Safety<br>▪ 393264 20GA BD Venflon Pro Safety<br>▪ 393266 18GA BD Venflon Pro Safety<br>▪ 393267 18GA BD Venflon Pro Safety<br>▪ 393268 17GA BD Venflon Pro Safety<br>▪ 393269 16GA BD Venflon Pro Safety<br>▪ 393270 14GA BD Venflon Pro Safety<br>**BD Venflon™ Pro Safety I.V. Cannula with Instaflash ™ Needle Technology**<br>▪ 393280 22GA BD Venflon Pro Safety I.V. Cannula with INSTAFLASH<br>▪ 393281 20GA BD Venflon Pro Safety I.V. Cannula with INSTAFLASH<br>▪ 393282 18GA BD Venflon Pro Safety I.V. Cannula with INSTAFLASH<br>▪ 393283 18GA BD Venflon Pro Safety I.V. Cannula with INSTAFLASH<br>▪ 393284 22GA BD Venflon Pro Safety I.V. Cannula with INSTAFLASH-INDIA<br>▪ 393285 20GA BD Venflon Pro Safety I.V. Cannula with INSTAFLASH-INDIA<br>▪ 393286 18GA BD Venflon Pro Safety I.V. Cannula with INSTAFLASH-INDIA<br>▪ 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:** | ▪ GMDN Code: 40601<br>▪ GMDN Term: Peripheral vascular catheter |

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



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.

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

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**REVISION HISTORY**

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. Haromonised standards were updated to reflect up to date information. | NA |
| B | Updated new notified body number | |

Do not include revision history page in page numbering.