

**TITLE: Declaration of Conformity for BD Venflon™ I.V. Cannula, BD Venflon I™ I.V. Cannula**  
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**EC DECLARATION OF CONFORMITY**

|                                     |   |
|-------------------------------------|---|
| <b>Legal Manufacturer:</b>          | Becton Dickinson Infusion Therapy AB<br>Florettgatan 29C, PO Box 631<br>SE-251 06 Helsingborg, Sweden   |
| <b>Manufacturing Site(s):</b>       | Becton Dickinson India Pvt. Ltd.<br>Plot No. 1, Sector 3, IMT, Bawal-123 501,<br>District Rewari, Haryana, India  |
| <b>Products:</b>                    | <p>BD Venflon™ I.V. Cannula</p> <ul style="list-style-type: none"> <li>▪ 391451 22GA BD Venflon I.V. Cannula</li> <li>▪ 391452 20GA BD Venflon I.V. Cannula</li> <li>▪ 391453 18GA BD Venflon I.V. Cannula</li> <li>▪ 391454 17GA BD Venflon I.V. Cannula</li> <li>▪ 391455 16GA BD Venflon I.V. Cannula</li> <li>▪ 391456 14GA BD Venflon I.V. Cannula</li> <li>▪ 391457 18GA BD Venflon I.V. Cannula</li> <li>▪ 391491 22GA BD Venflon I.V. Cannula (India)</li> <li>▪ 391492 20GA BD Venflon I.V. Cannula (India)</li> <li>▪ 391493 18GA BD Venflon I.V. Cannula (India)</li> <li>▪ 391495 16GA BD Venflon I.V. Cannula (India)</li> <li>▪ 391496 14GA BD Venflon I.V. Cannula (India)</li> </ul> <p>BD Venflon™ I I.V. Cannula</p> <ul style="list-style-type: none"> <li>▪ 391891 22GA BD Venflon I I.V. Cannula</li> <li>▪ 391892 20GA BD Venflon I I.V. Cannula</li> <li>▪ 391893 18GA BD Venflon I I.V. Cannula</li> <li>▪ 391895 16GA BD Venflon I I.V. Cannula</li> <li>▪ 391896 14GA BD Venflon I I.V. Cannula</li> <li>▪ 391591 22GA BD Venflon I I.V. Cannula (India)</li> <li>▪ 391592 20GA BD Venflon I I.V. Cannula (India)</li> <li>▪ 391593 18GA BD Venflon I I.V. Cannula (India)</li> <li>▪ 391595 16GA BD Venflon I I.V. Cannula (India)</li> <li>▪ 391596 14GA BD Venflon I I.V. Cannula (India)</li> </ul> |
| <b>Classification:</b>              | Class IIa, Annex IX, Rule 7   |
| <b>Conformity Assessment Route:</b> | Annex II, section 3.2   |
| <b>GMDN:</b>                        | <ul style="list-style-type: none"> <li>▪ GMDN Code: 64574</li> <li>▪ GMDN Term: Peripheral intravenous cannula</li> </ul>   |

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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| <b>Harmonised Standards:</b> | EN ISO 13485:2016<br>EN ISO 14971:2012 |
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|   | EN 20594-1:1993<br>EN 980:2008<br>EN ISO 10555-1:2014<br>EN ISO 10555-1:2013<br>EN ISO 10993-1:2009<br>EN ISO 10993-7:2008<br>EN ISO 11607-1:2009<br>EN ISO 11607-2:2006<br>EN 556-1:2001<br>EN ISO 11135-1:2014<br>EN ISO 11137-1:2006<br>EN ISO 11137-2:2009<br>EN ISO 15223-1:2016<br>EN 1041:2008<br>EN 62366:2008 |
| <b>Non-Harmonised Standards:</b>                    | ISO 594-2:1998<br>ISO 15223-1:2012<br>ISO 14644-1:1999<br>ISO 9626:1991<br>ISO 10555-1:2013<br>ISO 10555-5:2013  |
| <b>Notified Body:</b>                               | BSI Group, The Netherlands B.V.<br>Say Building, John M. Keynesplein 9<br>1066 EP, Amsterdam<br>Netherlands<br>Notified Body ID Number: 2797   |
| <b>CE Certificate Number:</b>                       | CE 597884  |
| <b>Date of issuance of original CE certificate:</b> | 11 January 1996  |

Date: 4<sup>th</sup> May 2020



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 Becton Dickinson Infusion Therapy, AB



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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 into SAP. Added in new Notified body number.      | NA                            |
| B   | Added signature  | N/A                           |
| C   | Added new SKU's for Venflon I  | N/A                           |
| D   | Updated India's manufacturing address<br>Added in new Venflon (India) SKUs | N/A                           |
| E   | Updated GMDN code  | N/A                           |

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