

Becton Dickinson Infusion Therapy AB  
 Florettgatan 29C, PO Box 631  
 SE-251 06 Helsingborg, Sweden  
 www.bd.com



## EC DECLARATION OF CONFORMITY

<b>Legal Manufacturer:</b>	Becton Dickinson Infusion Therapy AB Florettgatan 29C, PO Box 631 SE-251 06 Helsingborg, Sweden
<b>Manufacturing Site(s):</b>	Becton Dickinson India Pvt. Ltd. Plot No.1, Sector 3, IMT Bawal, District Rewari, Haryana - 123501 India
<b>Products:</b>	<b>BD Venflon™ I.V. Cannula</b> Catalog numbers: <ul style="list-style-type: none"> <li>• 391451 22GA</li> <li>• 391452 20GA</li> <li>• 391453 18GA</li> <li>• 391454 17GA</li> <li>• 391455 16GA</li> <li>• 391456 14GA</li> <li>• 391457 18GA</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: 40601</li> <li>▪ GMDN Term: Peripheral vascular catheter</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.

<b>Harmonised Standards:</b>	EN ISO 13485:2012 EN ISO 14971:2012 EN 20594-1:1993
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	EN ISO 10555-1:2009 EN ISO 10993-1:2009 EN ISO 10993-7:2008 EN ISO 11607-1:2009 EN ISO 11607-2:2006 EN 556-1:2001 EN ISO 11135-1: 2007 EN ISO 11737-1:2006 EN ISO 11737-2:2009 EN 980:2008 EN 1041:2008
<b>Non-Harmonised Standards:</b>	ISO 594-2:1998 ISO 15223-1:2012 ISO 14644-1:1999 ISO 9626:1991 ISO 10555-1:2013 ISO 10555-5:2013
<b>Notified Body:</b>	BSI Kitemark Court, Davy Avenue, Knowlhill Milton Keynes MK5 8PP United Kingdom Notified Body ID Number: 0086
<b>CE Certificate Number:</b>	CE 597884
<b>Date of issuance of original CE certificate:</b>	11 January 1996



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Becton Dickinson Infusion Therapy AB



Date