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

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, District Rewari, Haryana - 123501 India
Products:	**BD Venflon™ I.V. Cannula** Catalog numbers: • 391451 22GA • 391452 20GA • 391453 18GA • 391454 17GA • 391455 16GA • 391456 14GA • 391457 18GA
Classification:	Class IIa, Annex IX, Rule 7
Conformity Assessment Route:	Annex II, Section 3.2
GMDN:	▪ GMDN Code: 40601 ▪ GMDN Term: Peripheral vascular catheter

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 13485:2012 EN ISO 14971:2012 EN 20594-1:1993

	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
Non-Harmonised Standards:	ISO 594-2:1998 ISO 15223-1:2012 ISO 14644-1:1999 ISO 9626:1991 ISO 10555-1:2013 ISO 10555-5:2013
Notified Body:	BSI Kitemark Court, Davy Avenue, Knowlhill Milton Keynes MK5 8PP United Kingdom Notified Body ID Number: 0086
CE Certificate Number:	CE 597884
Date of issuance of original CE certificate:	11 January 1996

Name: Heather Hagvik
Function: Senior Regulatory Specialist
Becton Dickinson Infusion Therapy AB

2018.09.07

Date