

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



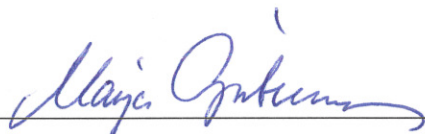
EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Becton Dickinson Infusion Therapy AB Florettgatan 29C, PO Box 631 SE-251 06 Helsingborg, Sweden
Manufacturing Site(s):	Becton Dickinson Infusion Therapy Systems Inc. S.A. de C.V., Periferico Luis Donaldo Colosio#579 Nogales, Sonora C.P. 84048 Mexico
Products:	BD Plug Luer-Lok™ Catalog number: <ul style="list-style-type: none">• 394080
Classification:	Class IIa, Annex IX, Rule 2
Conformity Assessment Route:	Annex II, Section 3.2
GMDN:	<ul style="list-style-type: none">▪ GMDN Code: 31667▪ GMDN Term: Catheter tip occluder

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 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
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Non-Harmonised Standards:	ISO 594-2:1998 ISO 15223-1:2012 ISO 14644-1:1999
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: Marja Gunnilstam
Function: Regulatory Affairs manager
Becton Dickinson Infusion Therapy AB



Date