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

BD
Helping all people live healthy lives

DECLARATION OF CONFORMITY

Manufacturer:	Becton Dickinson Infusion Therapy AB, Florettgatan 29C, PO Box 631, SE-251 06 Helsingborg, Sweden
Products:	**BD Connecta™ Stopcock with BD Q-Syte™ Luer Access** **Split-Septum** Catalog numbers: 394501, 394502
Classification:	Class IIa, Sterile BD Connecta™ Stopcock with BD Q-Syte™ Luer Access Split-Septum is a class IIa medical device Rule 2, Annex IX, MDD 93/42/EEC is applicable.
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 as amended. All supporting documentation is retained under the premises of the manufacturer.	
Conformity Assessment route:	Annex II
List of Harmonized standards:	EN ISO 11135-1: 2007 ISO 594-1:1986, ISO 594-2:1998 EN ISO 10993-1:2009 EN ISO 10993-7:2008 EN ISO 11607:2006 EN 980:2008 EN 1041:2008 EN ISO 13485:2003 EN ISO 9001:2008 EN ISO 14971:2009
Notified Body:	BSI ID 0086 Kitemark Court, Davy Avenue, Knowlhill Milton Keynes, MK5 8PP, UK Phone: 44 (0)845 080 9000
EC Certificate number:	597884
Start of CE marking:	October 2003
Manufacturing Site:	Becton Dickinson Infusion Therapy Systems Inc., S.A. de C.V., Periferico Luis Donaldo Colosio#579, Nogales, Sonora, C.P. 84048, Mexico

Name: Marja Gunnilstam
Function: Regulatory Affairs manager

2014-10-02
Date