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Revision Level: A

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EC DECLARATION OF CONFORMITY

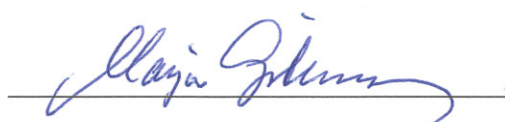
Legal Manufacturer:	Becton Dickinson Infusion Therapy AB Florettgatan 29C, PO Box 631 SE-251 06 Helsingborg, Sweden
Manufacturing Site(s):	Becton Dickinson Infusion Therapy Systems Inc. S.A. de C.V., Periferico Luis Donaldo Colosio#579 Nogales, Sonora C.P. 84048 Mexico
Products:	BD Connecta™ Stopcock BD Connecta™ Stopcock with extension tube BD Connecta™ Stopcock with injection valve and extension tube Catalog numbers: • 394600 BD Connecta™ • 395000 BD Connecta™ • 394601 BD Connecta™ • 394602 BD Connecta™ • 394605 BD Connecta™ • 394900 BD Connecta™ • 394901 BD Connecta™ • 394902 BD Connecta™ • 394905 BD Connecta™ • 394906 BD Connecta™ • 394908 BD Connecta™ • 394910 BD Connecta™ • 394911 BD Connecta™ • 394912 BD Connecta™ • 394926 BD Connecta™ 25 cm • 394936 BD Connecta™ 25 cm • 394945 BD Connecta™ 7 cm • 394951 BD Connecta™ 50 cm • 394961 BD Connecta™ 100 cm • 394971 BD Connecta™ 100 cm • 394982 BD Connecta™ 15 cm • 394983 BD Connecta™ 30 cm • 394995 BD Connecta™ 10 cm • 394997 BD Connecta™ 10 cm

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	• 395095 BD Connecta™ 10 cm • 395061 BD Connecta™ 100 cm
Classification:	Class IIa, Annex IX, Rule 2
Conformity Assessment Route:	Annex II, Section 3.2
GMDN:	▪ GMDN Code: 32172 ▪ GMDN Term: Infusion stopcock

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 11607-1:2009 EN ISO 11607-2:2006 EN 556-1:2001 EN ISO 11137-1:2006 EN ISO 11137-2:2013 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
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