

TITLE: Declaration of Conformity for BD Connecta™ Stopcock Products

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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	
Product Family:	Product Trade name:	Description:
BD Connecta™ Stopcocks	BD Connecta™	Stopcock with OFF directed tap without extension tube <ul style="list-style-type: none"> ▪ 394908 BD Connecta™ ▪ 394910 BD Connecta™ ▪ 394911 BD Connecta™ ▪ 394912 BD Connecta™
		Stopcock without extension tube <ul style="list-style-type: none"> ▪ 394600 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™ ▪ 395000 BD Connecta™ (INDIA)
		Stopcock with extension tube <ul style="list-style-type: none"> ▪ 394995 BD Connecta™ 10 cm ▪ 394997 BD Connecta™ 10 cm ▪ 394926 BD Connecta™ 25 cm ▪ 394951 BD Connecta™ 50 cm ▪ 394961 BD Connecta™ 100 cm ▪ 395095 BD Connecta™ 10 cm (INDIA) ▪ 395061 BD Connecta™ 100 cm (INDIA)
		Stopcock with low volume extension tube <ul style="list-style-type: none"> ▪ 394982 BD Connecta™ 15 cm ▪ 394983 BD Connecta™ 30 cm

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	Stopcock with extension tube and injection valve <ul style="list-style-type: none"> ▪ 394945 BD Connecta™ 7 cm ▪ 394936 BD Connecta™ 25 cm ▪ 394971 BD Connecta™ 100 cm
Classification:	Class IIa, Annex IX, Rule 2
Conformity Assessment Route:	Annex II, section 3.2
GMDN:	<ul style="list-style-type: none"> ▪ GMDN Code: 32172 ▪ GMDN Term: Intravenous line stopcock

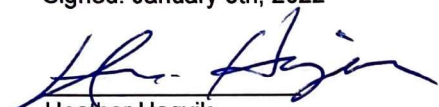
We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. All supporting documentation is retained at the premises of the manufacturer.

Harmonised Standards:	EN ISO 13485:2016 EN ISO 14971:2012 EN 20594-1:1993 EN ISO 10993-1:2018 EN ISO 11607-1:2017 EN ISO 11607-2:2017 EN 556-1:2001 EN ISO 11137-1:2015 EN ISO 11137-2:2015 EN ISO 11737-1:2018 EN ISO 11737-2:2009 EN 1041:2008 EN 62366:2015
Non-Harmonised Standards:	ISO 594-2:1998 ISO 15223-1:2012 ISO 14644-1:2015
Notified Body:	BSI Group, The Netherlands B.V. Say Building, John M. Keynesplein 9 1066 EP, Amsterdam Netherlands Notified Body ID Number: 2797
CE Certificate Number:	CE 597884

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original CE certificate:**

11 January 1996

Signed: January 5th, 2022



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<u>REVISION HISTORY</u>		
Current Version Prepared By: Heather Hagvik		
REV.	Revision Description	Releasing ECO (if applicable)
A	Initial Release, New DoC into SAP. Added in new Notified body number.	NA
B	Added signature	ECO
C	Updated DOC with Product trade name and product descriptions, updated newer standards in table	ECO
D	Updated the GMDN term	ECO

Do not include revision history page in page numbering.