

TITLE: Declaration of Conformity for BD Vecafix™ BD Veca-C™ I.V. Dressing

EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Becton Dickinson Infusion Therapy AB Florettgatan 29C, PO Box 631 SE-251 06 Helsingborg, Sweden
Manufacturing Site(s):	Manufactured for BD by: Attends Healthcare AB Järnvägsgatan 4 SE- 578 33 Aneby Sweden
Products:	BD Vecafix™ I.V. Dressing BD Veca-C™ I.V. Dressing <ul style="list-style-type: none"> ▪ 392015 ▪ 392020
Classification:	Class IS, Annex IX, Rule 1
Conformity Assessment Route:	Annex II, section 3.2
GMDN:	<ul style="list-style-type: none"> ▪ GMDN Code: 34864 ▪ GMDN Term: Adhesive bandage

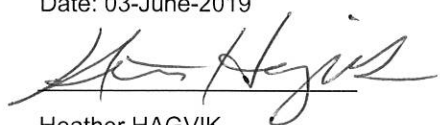
We herewith declare that the above mentioned products meet the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices. All supporting documentation is retained at the premises of the manufacturer.

Harmonised Standards:	EN ISO 13485:2016 EN ISO 14971:2012 EN ISO 10993-1:2009 EN ISO 10993-7:2008 EN 556-1:2001 EN ISO 11135-1:2017 EN 980:2008 EN 1041:2008
Non-Harmonised Standards:	ISO 15223-1:2012
Notified Body:	BSI Group, The Netherlands B.V. Say Buidling, John M. Keynesplein 9 Amsterdam 1066 EP

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	Netherlands Notified Body ID Number: 2797
CE Certificate Number:	CE 597884
Date of issuance of original CE certificate:	11 January 1996

Date: 03-June-2019



Heather HAGVIK
Senior Regulatory Specialist
Becton Dickinson Infusion Therapy, AB

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<u>REVISION HISTORY</u>		
Current Version Prepared By: Heather Hagvik		
REV.	Revision Description	Releasing ECO (if applicable)
A	New version in SAP. Updated new notified body number, and updated ISO 13485:2012 to ISO 13485:2016	NA
B	Added signature	N/A

[Do not include revision history page in page numbering.](#)