



BD Medical, Diabetes Care  
 1 Becton Drive  
 Franklin Lakes  
 New Jersey 07417  
 USA  
 Tel: (201) 847-6459  
 Fax: (201) 847-4856  
[www.bd.com](http://www.bd.com)

BD Medical-Diabetes Care  
 11 rue Aristide Bergès  
 ZI des Iles – BP4  
 38801 Le Pont de Claix Cedex  
 France  
 Tel: +33 (0)4.76.68.36.36  
 Fax: +33 (0)4.76.68.34.73  
[www.bd.com](http://www.bd.com)

**EC DECLARATION OF CONFORMITY**

<b>Legal Manufacturer:</b>	Becton Dickinson and Company 1 Becton Drive Franklin Lakes, New Jersey 07417, USA
<b>Authorised Representative:</b>	BD Medical – Diabetes Care Becton Dickinson France S.A.S. 11, rue Aristide Bergès, BP 4 38801 Le Pont-de-Claix Cedex, France
<b>Manufacturing Site(s):</b>	Nypro Precision Assemblies de Mexico S.A de C.V. Sor Juana Ines de la Cruz # 20150 Cd. Industrial Tijuana, Baja California CP 22444, Mexico
<b>Products:</b>	<b>BD Safe-Clip™</b> : REF 328455
<b>Classification:</b>	I, Annex IX, Rule 1
<b>Conformity Assessment Route:</b>	Annex VII
<b>GMDN:</b>	<ul style="list-style-type: none"> <li>▪ GMDN code: 38737</li> <li>▪ Term: Needle cutter</li> </ul>

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.

<b>Harmonised Standards</b>	EN 980:2008; EN 1041:2008; EN ISO 10993 series; EN ISO 13485:2012; EN ISO 14971:2012; EN ISO 22442-1:2007; EN ISO 14155:2011; EN ISO 62366: 2008
<b>Start of CE marking</b>	March 2005

This document has a validity of 5 years after issuance.

Date: May 2017

Aurélie CHAUDIER  
 Regulatory Affairs Manager  
 BD Medical -Diabetes Care EU

Date: 12 May 2017

Kathleen O'SULLIVAN, M.S., RAC  
 Worldwide Director Regulatory Affairs  
 BD Medical -Diabetes Care US