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EC DECLARATION OF CONFORMITY

Legal Manufacturer:	Becton Dickinson and Company 1 Becton Drive Franklin Lakes, New Jersey 07417 USA
Authorized Representative:	BD Medical – Diabetes Care Becton Dickinson France S.A.S. 11, rue Aristide Bergès, BP 4 38801 Le Pont-de-Claix Cedex France
Manufacturing Sites:	<ul style="list-style-type: none"> • Manufacture: Becton Dickinson and Company Pottery Road – Dun Laoghaire – Co. Dublin – Ireland • Sterilization: Becton Dickinson and Company Pottery Road – Dun Laoghaire – Co. Dublin – Ireland
Products:	<p>BD AutoShield™ Duo and BD SafeAssist™ Safety Pen Needles existing in the following presentations:</p> <ul style="list-style-type: none"> ▪ 0,30mm (30G) x 5mm: REF 329505, 329525, 329535, 329605, 329705, 329715, 329915, 329916 ▪ 0,30mm (30G) x 8mm: REF 329608, 329917, 329918
Classification:	Ila
Conformity Assessment Route:	Annex V and Annex VII
GMDN:	44127

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 under the premises of the manufacturer.

Harmonized standards:	EN 556-1:2001, EN ISO 15223-1:2016, EN 1041:2008, EN ISO 10993 series, EN ISO 11137-1:2015, EN ISO 11137-2:2015, EN ISO 11607-1:2009, EN ISO 11607-2:2006, EN ISO 11737-1:2006, EN ISO 11737-2:2009, EN ISO 13485:2016, EN ISO 14971:2012, EN 62366:2008
Non-Harmonized Standards:	ISO 11608-2:2012, ISO 9626:2016, ISO 2859-1:1999, ISO 10993-2:2006, ISO 10993-8:2001, ISO 11137-3:2006, EN ISO 23908:2013
Notified Body:	NSAI (National Standards Authority of Ireland) 1 Swift Square, Northwood, Santry, Dublin 9, Ireland Notified Body Number: 0050
CE Certificate number:	252.783
Date of issuance of original CE certificate:	29 January 2009

Date: 30 September 2020.....

Date: ...05-October-2020.....



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