EC Declaration of Conformity to:
Medical Devices Directive 93/42/EEC

Legal Manufacturer:	BD Switzerland Sàrl Route de Crassier 17, Business Park Terre-Bonne, Batiment A4, Eysins, CH-1262, Switzerland
EU Representative	Becton Dickinson Ireland Limited Donore Road Drogheda Co. Louth A92 YW26 Ireland
Manufacturing Site (s):	Integra Biotechnical, S.A. de C.V. Los Pinos Business Unit Avenida Ferrocarril No. 17030 Interior 8,16,17, Col. Ninos Heroes Este C.P. 22120, Tijuana Baja California, Mexico
Device Description/Family:	Texium™ Needle-Free Syringe *(See attached Product Schedule)*
EC Product Classification:	Class IIa, Annex IX, Rule 2
GMDN:	*47017 – General-purpose syringe* *A sterile device consisting of a calibrated barrel (cylinder) with plunger intended to be used to inject fluids (e.g., medication) into, and/or withdraw fluids/gas from, the body or a medical device for various medical applications. At the distal end of the barrel is a male connector (typically a Luer-lock type) for the attachment of the female connector (hub) of a hypodermic needle or an administration set. It is typically made of plastic and silicone materials and may have plunger anti-sticking properties (internally precoated with compatible substances) allowing smooth plunger movement, either manually or by a syringe pump. This is a single-use device.*

We herewith declare that the product(s) listed above and detailed in the attached Product Schedule meet the provisions of the Council Directive 93/42/EEC of 14 June 1993 concerning medical devices.

Applied Directives:	85/374/EEC - Product Liability 2006/121/EC – REACH 94/62/EC - Packaging and Packaging Waste Directive

Applied Standards	BS EN 556-1:2001/AC:2006 BS EN 1041:2008 +A1:2013 BS EN ISO 10993-1:2020 BS EN ISO 10993-4:2017 BS EN ISO 10993-5:2009 BS EN ISO 10993-10:2013 BS EN ISO 10993-11:2018

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	BS EN ISO 10993-12:2021 BS EN ISO 10993-16:2017 BS EN ISO 10993-17:2009 BS EN ISO 10993-18:2020 BS EN ISO 11137-1:2015+A2:2019 BS EN ISO 11137-2:2015 BS EN ISO 11607-1:2020/Corr:2020 BS EN ISO 11607-2:2020 BS EN ISO 11737-1:2018+A1:2021 BS EN ISO 11737-2:2020 BS EN ISO 13485:2016/+A11:2021 BS EN ISO 14644-1:2015 BS EN ISO 14644-2:2015 BS EN ISO 14644-5:2004 BS EN ISO 14971:2019+A11:2021 BS EN ISO 15223-1:2016/AC:2017 ISO 7886-1:1993 COR1 1995 ISO 7886-1:2017 (10mL Syringe only) BS EN 20594-1:1993/AC:1996 ISTA-1A - 2014 Edition ISTA-2A - 2012 Edition
Notified Body:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam. Notified Body Number: 2797 Former Notified Body: BSI Group, Kitemark Court, Davy Avenue, Knowlhill, Milton Keynes, MK5 8PP. Notified body number 0086
CE Certificate Number:	*Annex II (EC Certificate No. 502238)*
Date of issuance of original CE certificate:	16 November 2005

STED File: 305

Issue Level: 19

Signed:

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Signer Name: Roya Borazjani
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Roya Borazjani
VP, Regulatory Affairs
WW Infusion Preparation and Delivery

Date: 30-May-2022

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Product Schedule
Texium™ Needle-Free Syringe

GMDN Number: 47017

Part Number	Description	EC Product Class
MY8003-0006	BD Texium™ 3 mL Needle-Free Syringe	II a
MY8005-0006	BD Texium™ 5 mL Needle-Free Syringe	II a
MY8010-0006	BD Texium™ 10 mL Needle-Free Syringe	II a
MY8020-0006	BD Texium™ 20 mL Needle-Free Syringe	II a
MY8030-0006	BD Texium™ 30 mL Needle-Free Syringe	II a
MY8060-0006	BD Texium™ 50 mL Needle-Free Syringe	II a

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