

DECLARATION OF CONFORMITY

Legal Manufacturer:	Becton, Dickinson and Company 1 Becton Drive, Franklin Lakes, NJ 07417, USA
Authorized Representative:	Becton Dickinson Distribution Center Laagstraat 57. B-9140 Temse- Belgium
Manufacturing Site:	BD Caribe, Ltd Road 31, Km. 24.3, P.O. Box 4010, Juncos, PR 00777-4010 USA
Products:	400106 Needle Spinal S/SU 23G x 3 1/2" Quincke 400435 Needle Spinal BNS 18 G x 3 1/2" Quincke 400437 Needle Spinal BNS 22G x 2 1/2" Quincke 400440 Needle Spinal BNS 25G x 1" Neonatal 400441 Needle Spinal BNS 25G x 3" Quincke 400443 Needle Spinal BNS 25G x I 3mm Whitacre TW 400444 Needle Spinal BNS 27G x I 3mm Whitacre 400476 Needle Spinal BNS 26G x 3 1/2" Quincke 400477 Needle Spinal BNS 22G x I 1/2" Quincke 400479 Needle Spinal BNS 25G x 2" Quincke 400496 Needle Spinal BNS 25G x 3 1/2" Quincke 400497 Needle Spinal BNS 22G x 3 1/2" Quincke 400498 Needle Spinal BNS 20G x 3 1/2" Quincke 400540 Needle Spinal BNS 22G x 7" Quincke 400599 Needle Spinal BNS 25G x 4 1 1/16" Whitacre 400600 Needle Spinal BNS 27G x 4 1 1/16" Whitacre 400616 Needle Spinal BNS 24G x 3 1/2" Whitacre TW 400621 Needle Spinal BNS 25G x 3 1/2" Whitacre TW 400622 Needle Spinal B S 25G x 4 11/16" Whitacre TW 405010 Needle Spinal S/SU 22G x 3 1/2 " Whitacre 405071 Needle Spinal S/S U 20G x 2 1/2" Quincke 405073 Needle Spinal S/SU 25G x 1" Neonatal 405074 Needle Spinal S/SU 22G x 2 1/2" Quincke 405078 Needle Spinal S/SU 25G x 2" Quincke 405079 Needle Spinal S/SU 27G x 3 1/2" Whitacre 405081 Needle Spinal S/SU 27G x 3 1/2" Quincke 405133 Needle Spinal S/SU 24G x 3 1/2" Whitacre TW 405138 Needle Spinal S/SU 25G x 3 1/2" Whitacre TW 405140 Needle Spinal S /SU 25G x 5" Whitacre TW 405144 Needle Spinal S/SU 27G x 5" Whitacre 405148 Needle Spinal S /SU 22G x 5" Quincke

	405149 Needle Spinal S/SU 22G x 7" Quincke
	405155 Needle Spinal BNS 27G x 3 1/2" Quincke
	405157 Needle Spinal BNS 22G x 3 1/2" Whitacre
	405159 Needle Spinal S/SU 27G x 3 1/2" Whitacre
	405161 Needle Spinal S/SU 22G x 1 1/2" Quincke
	405162 Needle Spinal S/SU 20G x 1 1/2" Quincke
	405164 Needle Spinal /SU 26G x 3 1/2" Quincke
	405169 Needle Spinal BNS 25G x 11mm Whitacre
	405170 Needle Spinal S /SU 25G x 3" Quincke
	405171 Needle Spinal S/SU 22G x 3" Quincke
	405172 Needle Spinal S/SU 20G x 3" Quincke
	405174 Needle Spinal S/SU 18G x 3" Quincke
	405180 Needle Spinal S/SU 25G x 3 1/2" Quincke
	405181 Needle Spinal S/SU 22G x 3 1/2" Quincke
	405182 Needle Spinal S/S U 20G x 3 1/2" Quincke
	405184 Needle Spinal S/SU 18Gx 3 1/2" Quincke
	405211 Needle Spinal S/SU 20G x 6" Quincke
	405234 Needle Spinal S/SU 25G x 4-11/16" Quincke
	408360 Needle Spinal S/SU 18G x 6" Quincke
	409442 Needle Spinal S/SU 25G x 4-11/16" Whitacre
	409443 Needle Spinal S/SU 27G x 4-11/16" Whitacre
	400366 Needle Spinal S/SU 22GA 5IN Quincke CE
	400367 Needle Spinal S/SU 22GA 7IN Quincke CE
	400368 Needle Spinal S/SU 20GA 6IN Quincke CE
	400369 Needle Spinal S/SU 25GA 4-11/16IN Quincke CE
	400370 Needle Spinal S/SU 18GA 6IN Quincke CE
	400371 Needle Spinal S/SU 27GA 4-11/16IN Whitacre CE
	400372 Needle Spinal S/SU 25GA 4-11/16IN Whitacre CE
	400373 Needle Spinal S/SU 25GA TW 5IN Whitacre CE
	400374 Needle Spinal S/SU 27GA TW 5IN Whitacre CE
	400376 Needle Spinal S/SU 25GA 2IN Quincke CE
	400377 Needle Spinal S/SU 20GA 1-1/2IN Quincke CE
	400378 Needle Spinal S/SU 18GA 3IN Quincke CE
	400379 Needle Spinal S/SU 22GA 3-1/2IN Whitacre CE
	400380 Needle Spinal S/SU 27GA 3-1/2IN Whitacre CE
	400381 Needle Spinal S/SU 24GA TW 3-1/2IN Whitacre CE
	400382 Needle Spinal S/SU 25GA TW 3-1/2IN Whitacre CE

Classification:	Class III
Conformity Assessment Route:	Conformity Assessment route for this Class III product is Annex V (production quality assurance) coupled with Annex III (Type Testing)
GMDN information:	GMDN Code: 35212 GMDN Term: Spinal Anesthesia Needle, Single Use GMDN Definition: A sterile sharp bevel-edged, hollow tubular metal instrument designed to deliver anesthetic or analgesic agents intrathecally (in the space under the arachnoid membrane of the brain and spinal cord). It is typically fenestrated, spring-tipped, and used for short -term administration; it is typically made of metal and plastic materials. This is a single-use device.

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.

Standards of Conformance	<i>List of standards and their version</i>
	EN ISO 15223-1:2016 EN ISO 20594-1: 1993 EN ISO 1707: 1996 EN 1041: 2008 EN ISO 22442-1: 2020 EN 1707:1996 ISO 7864:1993 ISO 9626:1991 AMD1 2001 ISO 6009: 2016 ISO 10993-1:2018 EN ISO 11607-1:2020 EN ISO 11607-2: 2020 ISO 13485: 2016 ISO 14155: 2020 ISO 14971:2019 EN ISO 11135:2014/A1:2019 EN ISO 11138-1 :2017 EN ISO 11138-2:2017 EN 556-1:2001/AC:2006 EN ISO 11737-1:2018 EN ISO 11737-2: 2020 IEC 62366-1:2015 + AMD 2020

Notified Body:	National Standards Authority of Ireland (NSAI) I Swift Square, Northwood, Santry Dublin9, Ireland Notified Body Number: 0050 Phone : +353 I 807 3800 Fax: +353 I 807 3838 Email: info@nsai.ie Agencia Espanola de Medicamentos y Productos Sanitarios (AEMPS) Parque Empresarial Las Mercedes Edificio 8, Calle Campezo 11° I 28022 Madrid, Spain Notified Body Number:0318 Phone: +90 210 1322 Fax:+91 822 52 89
EC Certificate number.	252.797 (NSAI- Annex V) 201002 0698 ET (AEMPS- Annex III) 201002 0699 ET (AEMPS- Annex III) 201706 0860 ET (AEMPS- Annex III)
Start of CE marking:	Original Approval: 21 March 2010



Murtaza Rana

Function: Sr. Manager, Regulatory Affairs
BD Medical -Medication Delivery Solution

30 -November -2021
Date: