

BERPU 贝普	Document No.: ZSZ/CE-0801-01	Revision:A/3
Berpu Medical Technology Co., Ltd	Declaration of Conformity	Effective date: 2024-10-05


Effective

Sterile Hypodermic Needles for Single Use

Declaration of Conformity

according to medical device Regulation (EU) 2017/745

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Declaration of Conformity	
Manufacturer:	Berpu Medical Technology Co., Ltd. No.14 Xingji Road, Yongxing Street, Longwan District, 325000 Wenzhou, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA
Manufacturer SRN:	CN-MF-000012430
European Representative:	Shanghai International Holding Corp. GmbH (Europe) Eiffestrasse 80, 20537 Hamburg, Germany
Product Name:	Sterile Hypodermic Needles for Single Use
Model:	<p>Model 1: Sterile Hypodermic Needles for Single Use 0.18mm (34G), 0.20mm (33G), 0.23mm (32G), 0.25mm (31G), 0.3mm (30G), 0.33mm (29G), 0.36mm (28G), 0.4mm (27G), 0.45mm (26G), 0.5 mm (25G), 0.55 mm (24G), 0.6 mm (23G), 0.7 mm (22G), 0.8 mm (21G), 0.9 mm (20G), 1.1 mm (19G), 1.2 mm (18G), 1.5mm(17G), 1.6mm(16G), 1.8mm(15G), 2.1mm(14G), 2.4mm(13G), 2.7mm(12G)</p> <p>Model 2: Sterile Hypodermic Needles for Single Use (Self-sealing Hypodermic Needle) 0.18mm (34G), 0.20mm (33G), 0.23mm (32G), 0.25mm (31G), 0.3mm (30G), 0.33mm (29G), 0.36mm (28G), 0.4mm (27G), 0.45mm (26G), 0.5 mm (25G), 0.55 mm (24G), 0.6 mm (23G), 0.7 mm (22G), 0.8 mm (21G), 0.9 mm (20G), 1.1 mm (19G), 1.2 mm (18G)</p>
Intended purpose	The Sterile Hypodermic Needles for Single Use are used for medical purposes. It is used together with slip connector syringes or lock connector syringes to inject into or collect liquid from the body. It is disposable and treated as medical waste after use
Basic UDI-DI:	69492362N002QG
Device Group	A010101-HYPODERMIC NEEDLES
Risk Class of the Device:	Ila, Rule 6 according to Annex VIII of Regulation (EU) 2017/745 (MDR)
Conformity Assessment Path	Annex IX Chapters I and III of Regulation (EU) 2017/745
Standards:	EN ISO 7864:2016, EN ISO 9626:2020, EN ISO 14971:2019, EN ISO14644-1:2015, EN ISO 14644-2:2015, EN ISO 20417:2021, EN ISO 15223-1:2021, EN ISO 10993-1:2020, EN ISO10993-4:2017, EN ISO 10993-5:2009, EN ISO 10993-7:2008/AC:2009, EN ISO 10993-10:2021, EN ISO 10993-23:2021, EN ISO 10993-11:2018, EN ISO 11737-1:2018, EN ISO 11607-1:2020, EN ISO11607-2:2020, EN 17141:2020, EN ISO 11135:2014
Statement	We hereby declare that the stated medical device meet the transposition into national

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	law, the provisions of Regulation (EU) 2017/745.All supporting documentation is retained at the premises of the manufacturer, and the manufacturer is exclusively responsible for the Declaration of Conformity
Notified Body:	TÜV SÜD Product Service GmbH Zertifizierstellen Ridlerstraße 65, 80339 MÜNCHEN, Germany
Identification number:	CE ₀₁₂₃
(EC)Certificate(s)	G10 093930 0010 Rev.01
Exp.date	2027-12-13
Start of CE-marking:	2022-12-14
Place,Date of Declaration:	Wenzhou, 2024-10-05
Signature: Name: Position:	Buxin Yu  Management Representative

Article List

Article No.	Product Name	Size	Bevel
4656300B	Sterican®	0.30 x 12 mm (30G x ½")	Long Bevel
4665457B	Sterican®	0.45 x 12 mm (26G x ½")	Long Bevel
4657683B	Sterican®	0.45 x 25 mm (26G x 1")	Long Bevel
4665406B	Sterican®	0.40 x 12 mm (27G x ½")	Long Bevel
4657705B	Sterican®	0.40 x 20 mm (27G x ¾")	Long Bevel
9186174B	Sterican®	0.40 x 25 mm (27G x 1")	Long Bevel
9186182B	Sterican®	0.40 x 40 mm (27G x 1 ½")	Long Bevel
4657675B	Sterican®	0.55 x 25 mm (24G x 1")	Long Bevel
4657853B	Sterican®	0.50 x 16 mm (25G x ⅝")	Long Bevel
9186158B	Sterican®	0.50 x 25 mm (25G x 1")	Long Bevel
9186166B	Sterican®	0.50 x 40 mm (25G x 1 ½")	Long Bevel
4657667B	Sterican®	0.60 x 25 mm (23G x 1")	Long Bevel
4657640B	Sterican®	0.60 x 30 mm (23G x 1 ¼")	Long Bevel
4666410B	Sterican®	0.60 x 40 mm (23G x 1 ½")	Long Bevel
4665600B	Sterican®	0.60 x 60 mm (23G x 2 ⅜")	Long Bevel
4665635B	Sterican®	0.60 x 80 mm (23G x 3 ⅛")	Long Bevel
4657624B	Sterican®	0.70 x 30 mm (22G x 1 ¼")	Long Bevel
4660021B	Sterican®	0.70 x 40 mm (22G x 1 ½")	Long Bevel
4650018B	Sterican®	0.70 x 50 mm (22G x 2")	Long Bevel

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4665643B	Sterican®	0.80 x 120 mm (21G x 4 ¾")	Long Bevel
4657543B	Sterican®	0.80 x 25 mm (21G x 1")	Long Bevel
4657527B	Sterican®	0.80 x 40 mm (21G x 1 ½")	Long Bevel
4665503B	Sterican®	0.80 x 50 mm (21G x 2")	Long Bevel
4665465B	Sterican®	0.80 x 80 mm (21G x 3 ⅛")	Long Bevel
4657500B	Sterican®	0.90 x 25 mm (20G x 1")	Long Bevel
4657519B	Sterican®	0.90 x 40 mm (20G x 1 ½")	Long Bevel
4667093B	Sterican®	0.90 x 50 mm (20G x 2")	Short Bevel
4665791B	Sterican®	0.90 x 70 mm (20G x 2 ¾")	Long Bevel
4665317B	Sterican®	1.10 x 30 mm (19G x 1 ¼")	Long Bevel
4657799B	Sterican®	1.10 x 40 mm (19G x 1 ½")	Long Bevel
4665112B	Sterican®	1.10 x 40 mm (19G x 1 ½")	Short Bevel
4665511B	Sterican®	1.10 x 50 mm (19G x 2")	Long Bevel
4650034B	Sterican®	1.20 x 40 mm (18G x 1 ½")	Long Bevel
4665120B	Sterican®	1.20 x 40 mm (18G x 1 ½")	Short Bevel
4667123B	Sterican®	1.20 x 50 mm (18G x 2")	Short Bevel
4665473B	Sterican®	2.10 x 80 mm (14G x 3 ⅛")	Short Bevel