

BERPU 贝普	Document No. :YSZ/CE-0801	Revision:A/2
Berpu Medical Technology Co., Ltd	Declaration of Conformity	Effective date: 2023-02-07

Sterile Insulin Pen Needles for Single Use **Declaration of Conformity**

according to medical device Regulation (EU) 2017/745

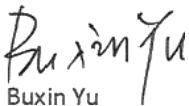
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Declaration of Conformity

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 SRN: DE-AR-000000001												
Product Name:	Sterile Insulin Pen Needles for Single Use												
Model:	0.18mm(34G),0.20mm(33G),0.23mm(32G),0.25mm(31G),0.3mm(30G),0.33mm(29G) 0.36mm(28G)												
Trade REF	<table><tr><th>REF#</th><th>SIZE</th></tr><tr><td>I23204</td><td>32GX4MM</td></tr><tr><td>I23105</td><td>31GX5MM</td></tr><tr><td>I23106</td><td>31GX6MM</td></tr><tr><td>I23108</td><td>31GX8MM</td></tr></table>			REF#	SIZE	I23204	32GX4MM	I23105	31GX5MM	I23106	31GX6MM	I23108	31GX8MM
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I23204	32GX4MM												
I23105	31GX5MM												
I23106	31GX6MM												
I23108	31GX8MM												
Intended purpose	The Sterile Insulin pen needles for Single Use is intended for medical purpose to use with pen injector devices for the subcutaneous injection of insulin. It can only be used once and shall be disposed as medical waste after use.												
Basic UDI-DI:	69492362N001QE												
Deyce Group	A010101-HYPODERMIC NEEDLES												
Risk Class of the Device:	IIa, 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 9626:2016,ISO 11608-2:2022, 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 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:	TUV suD Product Service GmbH Zertifizierstellen RidlerstraBe 65,80339 MUNCHEN, Germany												

Identification number:	CE0123
(EC)Certificate(s)	G100939300010 Rev.01
Exp.date	2027-12-13
Start of CE-marking:	2024-09-23
Place,Date of Declaration:	Buxin Yu Buxin Yu Wenzhou,2025-02-07

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Signature:	
Name:	Buxin Yu
Position:	Management Representative