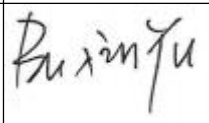
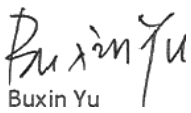
Sterile Insulin Pen Needles for Single Use
Declaration of Conformity

according to medical device Regulation (EU) 2017/745

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	REF# / SIZE 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
Deyice Group	A010101-HYPODERMIC NEEDLES
Risk Class of the Device:	lla, Rule 6 according to Annex Vlll of Regulation (EU) 2017/745(MDR)
Conformity Assessment Path	Annex IX Chapters l and lll 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:	CE 0123
(EC)Certificate(s)	G100939300010 Rev.00
Exp.date	2027-12-13
Start of CE-marking:	2022-12-14
Place,Date of Declaration:	 Buxin Yu Wenzhou,2023-02-07

Signature: Name: Position:	 Buxin Yu Management Representative