Sterile Hypodermic 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
Product Name:	Sterile Hypodermic Needles for Single Use
Model:	Model 1 • Outside diameter of the needle tubing: 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),1.4mm(17G),1.6mm(16G),1.8mm(15G),2.1mm(14G) • Effective needle length: 4mm-120mm Model 2 Self-sealing Hypodermic Needle: R • Outside diameter of the needle tubing: 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) • Effective needle length: 4mm-45mm;
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
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 9626:2020, 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 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)	No. G10 093930 0010 Rev. 00
Exp.date	2027-12-13
Start of CE-marking:	2022-12-14
Place,Date of Declaration:	Wenzhou, 2024-07-10
Signature: **Name:** **Position:**	Yu. Buxin Buxin Yu Management Representative