

|  |                                     |                               |
|--|-------------------------------------|-------------------------------|
| <b>BERPU</b><br>贝普                       | <b>Document No.:</b> ZSZ/CE-0801-01 | Revision:A/0                  |
| <b>Berpu Medical Technology Co., Ltd</b> | <b>Declaration of Conformity</b>    | Effective date:<br>2023-04-19 |

Effective

# Sterile Hypodermic Needles for Single Use

## Declaration of Conformity

according to medical device Regulation (EU) 2017/745

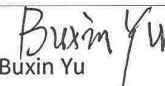
Effective

|  |                                     |                               |
|--|-------------------------------------|-------------------------------|
| <b>BERPU</b><br>贝普                       | <b>Document No.:</b> ZSZ/CE-0801-01 | Revision:A/0                  |
| <b>Berpu Medical Technology Co., Ltd</b> | <b>Declaration of Conformity</b>    | Effective date:<br>2023-04-19 |

| <b>Declaration of Conformity</b>  |   |
|-----------------------------------|---|
| <b>Manufacturer:</b>              | Berpu Medical Technology Co., Ltd.<br>No.14 Xingji Road, Yongxing Street, Longwan District, 325000 Wenzhou, Zhejiang Province,<br>PEOPLE'S REPUBLIC OF CHINA  |
| <b>Manufacturer SRN:</b>          | CN-MF-000012430   |
| <b>European Representative:</b>   | Shanghai International Holding Corp. GmbH (Europe)<br>Eiffestrasse 80, 20537 Hamburg, Germany   |
| <b>Product Name:</b>              | Sterile Hypodermic Needles for Single Use   |
| <b>Model:</b>                     | Model 1: Sterile Hypodermic Needles for Single Use<br>0.18mm (34G), 0.20mm (33G), 0.23mm (32G), 0.25mm (31G), 0.3mm (30G), 0.33mm (29G),<br>0.36mm (28G), 0.4mm (27G), 0.45mm (26G), 0.5 mm (25G), 0.55 mm (24G), 0.6 mm (23G), 0.7<br>mm (22G), 0.8 mm (21G), 0.9 mm (20G), 1.1 mm (19G), 1.2 mm (18G)<br>Model 2 :Sterile Hypodermic Needles for Single Use (Self-sealing Hypodermic Needle)<br>0.18mm (34G), 0.20mm (33G), 0.23mm (32G), 0.25mm (31G), 0.3mm (30G), 0.33mm (29G),<br>0.36mm (28G), 0.4mm (27G), 0.45mm (26G), 0.5 mm (25G), 0.55 mm (24G), 0.6 mm (23G), 0.7<br>mm (22G), 0.8 mm (21G), 0.9 mm (20G), 1.1 mm (19G), 1.2 mm (18G) |
| <b>Intended purpose</b>           | The Sterile Hypodermic Needles for Single Use are used for medical purposes. It is used together<br>with slip connector syringes or lock connector syringes to inject into or collect liquid from the<br>body. It is disposable and treated as medical waste after use  |
| <b>Basic UDI-DI:</b>              | 69492362N002QG  |
| <b>Device Group</b>               | A010101-HYPODERMIC NEEDLES  |
| <b>Risk Class of the Device:</b>  | IIa, Rule 6 according to Annex VIII of Regulation (EU) 2017/745 (MDR)   |
| <b>Conformity Assessment Path</b> | Annex IX Chapters I and III of Regulation (EU) 2017/745   |
| <b>Standards:</b>                 | EN ISO 7864:2016, EN ISO 9626:2016, EN ISO 14971:2019, EN ISO14644-1:2015,<br>EN ISO 14644-2:2015, EN ISO 20417:2021, EN ISO 15223-1:2021, EN ISO 10993-1:2020, EN<br>ISO10993-4:2017, EN ISO 10993-5:2009, EN ISO 10993-7:2008/AC:2009, EN ISO 10993-10:2021, EN ISO<br>10993-23:2021, EN ISO 10993-11:2018, EN ISO 11737-1:2018, EN ISO 11607-1:2020, EN ISO11607-2:2020,<br>EN 17141:2020, EN ISO 11135:2014   |
| <b>Statement</b>                  | We hereby declare that the stated medical device meet the transposition into national law, the<br>provisions of Regulation (EU) 2017/745. All supporting documentation is retained at the<br>premises of the manufacturer, and the manufacturer is exclusively responsible for the<br>Declaration of Conformity   |
| <b>Notified Body:</b>             | TÜV SÜD Product Service GmbH Zertifizierstellen<br>Ridlerstraße 65, 80339 MÜNCHEN, Germany  |

|  |                                     |                               |
|--|-------------------------------------|-------------------------------|
| <b>BERPU</b><br>贝普                       | <b>Document No.:</b> ZSZ/CE-0801-01 | Revision:A/0                  |
| <b>Berpu Medical Technology Co., Ltd</b> | <b>Declaration of Conformity</b>    | Effective date:<br>2023-04-19 |

Effective

|                                   |   |
|-----------------------------------|---|
| <b>Identification number:</b>     | CE 0123   |
| <b>(EC)Certificate(s)</b>         | G10 093930 0010 Rev.00  |
| <b>Exp.date</b>                   | 2027-12-13  |
| <b>Start of CE-marking:</b>       | 2022-12-14  |
| <b>Place,Date of Declaration:</b> | Wenzhou,2023-04-19  |
| <b>Signature:</b>                 |  |
| <b>Name:</b>                      | Buxin Yu  |
| <b>Position:</b>                  | 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 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 ⅞")  | 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 |
| 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 ⅞")  | Long Bevel |

Effective

Effective

|  |                                     |                               |
|--|-------------------------------------|-------------------------------|
| <b>BERPU</b><br>贝普                       | <b>Document No.:</b> ZSZ/CE-0801-01 | Revision:A/0                  |
| <b>Berpu Medical Technology Co., Ltd</b> | <b>Declaration of Conformity</b>    | Effective date:<br>2023-04-19 |

|          |           |                           |             |
|----------|-----------|---------------------------|-------------|
| 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 |

Effective