Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-099

Effective
TÜV SÜD Product Service

EU Quality Management System Certificate (MDR)

Pursuant to Regulation (EU) 2017/745 on Medical Devices, Annex IX Chapters I and III (Class IIa and Class IIb Devices)

No. G10 093930 0010 Rev. 01

Manufacturer:

Berpu Medical Technology Co., Ltd
No.14 Xingji Road
Yongxing Street, Longwan District
325000 Wenzhou, Zhejiang Province
PEOPLE'S REPUBLIC OF CHINA

SRN Manufacturer - CN-MF-000012430

Authorized Representative:

Shanghai International Holding Corp. GmbH (Europe)
Eiffestraße 80, 20537 Hamburg, GERMANY

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (9) of the Regulation (EU) 2017/745 on medical devices. Details on device categories covered by the quality management system are described on the following page(s). The Report referenced below summarises the result of the assessment and includes reference to relevant CS, harmonized standards and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.
The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.
The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment shall also include an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples. All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.
For details and certificate validity see: www.tuvsud.com/ps-cert?q=cert:G10 093930 0010 Rev. 01

Report No.: BJ23084404

Preceding Certificate No.: G10 093930 0010 Rev. 00

Valid from: 2024-09-23
Valid until: 2027-12-13

Date of Initial Issuance: 2022-12-14

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2024-09-23

Effective

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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No. G10 093930 0010 Rev. 01

Classification:	Class IIa
Device Group:	A010101 - HYPODERMIC NEEDLES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A010105 - NEEDLES FOR COLLECTION UNDER VACUUM
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A010601 - CARPULE NEEDLES
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A020102 - INFUSION AND IRRIGATION SYRINGES, SINGLE-USE
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A020106 - INSULIN SYRINGES, SINGLE-USE
Intended Purpose:	-

Classification:	Class IIa
Device Group:	A010102 - BUTTERFLY NEEDLES
Intended Purpose:	-

The validity of this certificate depends on conditions and/or is limited to the following:	-none-

Revision History:

Rev.	Dated	Report	Description
00	2022-12-14	BJ22084401	-
01	2024-09-23	BJ23084404	Supplemented: Device(s)/group of device(s) added

Effective

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TÜV SÜD Product Service GmbH • Certification Body • Ridlerstraße 65 • 80339 Munich • Germany

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