EU Certificate

Quality Management System
REGULATION (EU) 2017/745 on Medical Devices, Annex IX Chapter I, Section 2 and 3 and Chapter III

TÜVRheinland®

Registration No.: HZ 2365565-1

Manufacturer: **Beijing Fert Technology Co., Ltd.**
1st and 2nd floors of Building 3, Building 4, Courtyard 23,
Panlong West Road, Mafang Town, Pinggu District,
101204 Beijing
P.R. China

EUDAMED Single Registration No.: CN-MF-000009737

Products:

Product of Class IIa:
C01010101 - PERIPHERAL I.V. CATHETERS, W/O SAFETY SYSTEMS
C01010102 - PERIPHERAL I.V. CATHETERS, WITH SAFETY SYSTEMS
A01010102 - HYPODERMIC PEN NEEDLES

Product of Class IIb:
A020203 - REUSABLE SYRINGES
CARTRIDGE SYRINGES

Authorised representative(s): Lepu Medical (Europe) Cooperatief U.A.
Abe Lenstra Boulevard 36, 8448JB, Heerenveen, Netherlands

Certificate history		
Revision:	Description:	Issue date:
0	Initial Revision	2023-08-28

The Notified Body hereby declares that the requirements of Annex IX, Chapter I, Section 2 and 3 of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a quality management system, which is subject to periodic surveillance, defined by Annex IX, Chapter I, Section 3 of the aforementioned regulation. The requirements of Annex IX, Chapter III are fulfilled. If class III devices or class IIb implantable devices referred to in the second subparagraph of Article 52(4) are covered by this certificate an EU technical documentation assessment certificate according to Chapter II, Section 4.9 is required before placing them on the market.

Report No.: 190138977-120

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TÜV Rheinland LGA Products GmbH Zertifizierungsstelle TÜVRheinland

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Benannt durch/Designated by
Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten
www.zlg.de
BS-MDR-091

TÜV Rheinland LGA Products GmbH is a Notified Body according to REGULATION (EU) 2017/745 concerning medical devices with the identification number 0197.