EU Certificate

Production Quality Assurance
REGULATION (EU) 2017/745 on Medical Devices, Annex XI, Part A

TÜVRheinland®

Registration No.:	DZ 2302587-1
Manufacturer:	**Liaoning KANGYI Medical Equipment Co., Ltd.** No.34, Meicheng West Road, Haizhou District, Fuxin City, 123000 Liaoning, P.R. China
EUDAMED Single Registration No.:	CN-MF-000011926
Products:	Products of Class IIa A020102 INFUSION AND IRRIGATION SYRINGES, SINGLE-USE A030401 INFUSION KITS (INCLUDING THOSE VIA PUMP), SINGLE-USE
Authorised representative(s):	**MedPath GmbH** Mies-van-der-Rohe-Strasse 8, 80807 Munich, Germany

Certificate history		
Revision:	Description:	Issue date:
0	Initial	2022-01-11

The Notified Body hereby declares that the requirements of Annex XI, Part A of the REGULATION (EU) 2017/745 have been met for the listed products. The above named manufacturer has established and applies a production quality assurance, which is subject to periodic surveillance, defined by Annex XI, Part A, Section 7 of the aforementioned regulation. If class III devices or class IIb devices are covered by this certificate, an EU type-examination certificate in accordance with Annex X of the aforementioned regulation is required before placing them on the market.

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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 Zertifizierstelle

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