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 2086546-1

Manufacturer: **Shanghai Health Medical Co., Limited**
No.79 North Qingyang Road, Tianning District
Changzhou
213017 Jiangsu
P.R. China

EUDAMED Single Registration No.: CN-MF-000021112

Products: Products of class I, sterile:
A030101 - INFUSION CONTROLLERS
Infusion Set
A030201 - EXTENSIONS
Extension Tube
A060303 - URINE COLLECTION SYSTEMS AND BAGS, SINGLE-USE
Urine Bag
A0703 - STOPCOCKS
Three WAY Stopcock
A070501 - CAPS OR OBTURATORS, NON-PERFORABLE
Infusion Connector
A070502 - CAPS OR OBTURATORS, PERFORABLE
Needle Free Connector
A070599 - CAPS OR OBTURATORS - OTHER
Infusion Connector
The scope of certification is limited to the aspects relating to establishing, securing and maintaining sterile conditions

Authorised representative(s): Riomavix S.L.
Calle de Almansa 55, 1D, Madrid 28039 Spain

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.: 244457942-200

Effective date: 2023-06-21

Expiry date: 2028-06-20

Issue date: 2023-06-21

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

Herbert Zhong
TÜV Rheinland LGA Products GmbH
Tillystraße 2 · 90431 Nürnberg · Germany

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

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

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Manufacturer: **Shanghai Health Medical Co., Limited**
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Certificate history		
Revision:	Description:	Issue date:
0	Initial Revision	2023-06-21

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