Shanghai International Holding Corporation GmbH (Europe)
Eiffestrasse, 80, D-20537 Hamburg Germany
Tel: +49 40 2513175 Fax: +49 40 255726

Confirmation dated on March 22nd, 2023

Herewith we confirm that we are the European authorised representative of the following devices manufactured by Suzhou Juneland Medical Co., Ltd. (Add: No.3, 5 Liuzhuang Road, Mudu Town, Wuzhong District, 215000 Suzhou, P.R. China) according to the requirements set out in Directive 93/42/EEC (MDD) and article 120 of Regulation (EU) 2017/745 (MDR):

1. Suction Drainage Tube, Irrigation Set, Sterile Surgical and Care Kit
(The devices are classified as IIa medical devices and have a certificate numbered G2 002318 0002 Rev. 01 issued by TUV SUD in accordance with MDD)
2. Drainage Bag (The device is classified as I Sterile medical device and has a certificate numbered G2S 002318 0003 Rev. 01 issued by TUV SUD in accordance with MDD)

We also confirm that:
In accordance with Regulation (EU) 2023/607 of the European Parliament and of the Council amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices, which has entered into force on March 20th, 2023 of its publication in the Official Journal of the European Union and shall be directly applicable in all Member States, the above-mentioned CE certificates shall remain valid after the end of the period indicated on the certificates until end of 2028 only if the following conditions are met:

(a) the devices continue to comply with MDD;
(b) there are no significant changes in the design and intended purpose;
(c) the devices do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;
(d) no later than 26 May 2024, the manufacturer has put in place a quality management system in accordance with Article 10(9) of MDR;
(e) no later than 26 May 2024, the manufacturer has lodged a formal application with a notified body in accordance with Section 4.3, first subparagraph, of Annex VII of MDR for conformity assessment in respect of the above-mentioned devices or in respect of the devices intended to substitute the above-mentioned devices, and, no later than 26 September 2024, the notified body and the manufacturer have signed a written agreement in accordance with Section 4.3, second subparagraph, of Annex VII of MDR for conformity assessment.

The regulation of extension aims to ensure an avoidance of shortages of medical devices needed for the smooth functioning of healthcare services, without lowering current quality or safety requirements. The extensions of the validity of the above-mentioned CE certificates are directly applicable, so that TUV SUD is not required to change the dates on the certificates. Our term of the authorised representing for the above-mentioned devices will be extended accordingly and TUV SUD shall also continue to be responsible for the appropriate surveillance in respect of the applicable requirements relating to the devices.

Best regards,

Shanghai International Holding Corporation GmbH (Europe) Eiffestrasse 80 20537 Hamburg

Mr. Liang Jin
Legal representative of Shanghai International Holding Corp. GmbH (Europe)