

EC Declaration of Conformity

Regarding Medical Device Regulation (EU) 2017/745

Manufacturer

Name: Com-Bridge International Co., Ltd.

Address: Unit 1, NO. 66 Yulong 3 Road, Dong Sheng Town, 528400, Zhongshan, Guangdong China

European Authorized Representative:

Name: MedNet EC-Rep GmbH

Address: Borkstrasse 10, 48163 Münster, Germany

SRN: DE-AR-000000002

Product

Name: Commode

Basic UDI-DI: 69738060010288J

Classification: I

Rule: According to the classification rule 1, Annex VIII, Chapter III of Medical Device Regulation (EU) 2017/745

Conformity Assessment Route

Annex II+III in Medical Device Regulation (EU) 2017/745

We, the manufacturer confirm our products meet the requirements of Medical Device Regulation (EU) 2017/745 and the following applied standards:

EN 1041:2008, ISO 15223-1:2021, EN ISO 13485:2016, EN ISO 14971:2019, ISO10993-1:2018, ISO 10993-5:2016, ISO 10993-10:2016, ISO 17966:2016 IEC 62366:2015, MEDDEV 2.7/1 rev 4, MEDDEV 2.12/1 rev 8

The manufacturer is exclusively responsible for the declaration of conformity.

General Manager:  王冬梅

Com-Bridge International Co.,Ltd.

On June 24, 2021 in Zhong Shan City