EU Declaration of Conformity

The following description for the medical device,

Device information	*Description*
Registered trade name and address	*HEBEI Healthplus Medical Device Co., Ltd.* *No. 1, Chuangye Street, Southwest Industrial District, Matou Ecological Industry Park, Handan city, Hebei, 056046, China* *Tel:+86-0310-2111888*
Authorized representative	*Y. Sung Handelsvertretung* *Toulouser Allee 9, 40211 Duesseldorf, Germany*
Common device name	*Bath Chairs / Shower Chairs*
Product code	*HE10678103/HE10688023/HE13741000/HE10635081*
Product and trade name	Healthplus User Friendly 凯普威 Medical Products
UMDNS code	***10788**: Bath Chairs / **10802**: Shower Chairs*
GMDN code	***34936**: Chair, Bath / Shower*
Registration Number (SRN)	**Manufacturer: CN-MF-000013062** **Authorized representative: DE-AR-000005142**
Basic UDI-DI	*Bath Chairs: **697322200COMMODEM6*** *Shower Chairs: **697322200BABDBD***
Risk class of the device	*Class I*
Common Specification (CS) references	*Shower Chair, Shower Chair with Back,* *Bath Chair / Bench*
Intended purpose (GMDN definition)	*A device designed to support the back, and sometimes buttocks, of a patient (usually an adult) who is bathing in a bath (usually while being attended/assisted) to enable the patient to sit in an upright, and sometimes elevated, position in the bath. The patient is typically disabled, infirm, or undergoing medical treatment and cannot sit normally in a bath. The device may be a back rest only or a seat with an incorporated back rest, typically made of water-resistant or waterproof materials; it may be laid across the rim of the bath or secured to the bath. The device may be used in a hospital, institution, or home.*

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That is covered by the present declaration is in conformity with the Medical Device Regulation 2017/745/EU as amended by 2020/561/EU:

For the evaluation regarding Class I device (Risk class in accordance with the Rule 1 set out in Annex VIII of EU 2017/745), the following harmonized standards are applied:

- *EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes*
- *EN ISO 14971:2019 Medical devices— Application of Risk Management*
- *EN ISO 15223-1:2021 Medical device – Symbols to be used with medical device labels, labelling and information to be supplied – Part 1: General requirements*
- *EN 62366-1:2015 Medical devices Part 1-- Application of usability engineering to medical devices*

The following Union authorized representative is stated to the declaration:

Y. Sung Handelsvertretung
Toulouser Allee 9, 40211 Duesseldorf, Germany

(Company name / Registered place of business)

The following person is exclusively responsible for the compliance of declaration:

HEBEI Healthplus Medical Device Co., Ltd.
No. 1, Chuangye Street, Southwest Industrial District, Matou Ecological Industry Park, Handan city, Hebei, 056046, China

(Manufacturer's name/ Registered address)

Dickson Su / General Manager *May 15, 2022*

(Name/Function) (Legal Signature) (Date of issue)