EU Declaration of Conformity

The following description for the medical device,

Device information	*Description*
Registered trade name and address	*Homecare Enterprise Co., Ltd.* *No. 488, Lunmei Road, Changhua City, Changhua County 500, Taiwan (R.O.C.)* *Tel:+886-4-7627651*
Authorized representative	*KOMAS Medical Technology GmbH* *Sternstraße 67, 40479 Düsseldorf, Deutschland*
Common device name	*Bath Chairs / Shower Chairs*
Product and trade name	*HOMCARE*
UMDNS code	***10788**: Bath Chairs / **10802**: Shower Chairs*
GMDN code	***34936**: Bath Back Rest / Seat*
Single Registration Number (SRN)	***TW-MF-000012356***
Product representative model number designated Basic UDI-DI	*Plastic wood shower chair with Back,* *5403BW 5319ADJ* ***#4710701880035***
Risk class of the device	*Class I*
Common Specification (CS) references	*Plastic wood shower chair with Back*
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.*
Conformity assessment procedure performed and identification of the certificates issued by notified body, if applicable	*Quality Management System* *ISO 13485:2016 by ASR* *ISO 14001: 2015 by UDEM*
Name and identification number of the notified body, if applicable	*American System Registrar, LLC: ASR* *ASR Certificate Number: 7532* *Uluslararasi Belgelendirme Denegim Egitim Merkezi* *UDEM Certificate Number: 61458*

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that is covered by the present declaration is in conformity with the Medical Device **Regulation 2017/745/EU** and, if applicable, with any other relevant Union legislation that provides for the issuing of this EU declaration of conformity. The device is in conformity with conformity assessment procedure for **Class I devices** that should be carried out, as a general rule, under the sole responsibility of manufacturers in view of the low level of vulnerability associated with such devices. Thus, manufacturers of class I devices, other than custom-made or investigational devices, shall declare the conformity of their products by issuing an EU declaration of conformity referred to in Article 19 "EC declaration of conformity" after drawing up the technical documentation set out in Annexes II and III of the **Regulation**.

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

- *EN ISO 13485:2016 Medical devices - Quality management systems - Requirements for regulatory purposes*
- *EN ISO 14971:2012 Medical devices－Application of Risk Management*
- *EN ISO 15223-1:2016 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:

KOMAS Medical Technology GmbH Sternstraße 67, 40479 Düsseldorf, Deutschlandy

(Company name / Registered place of business)

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

Homecare Enterprise Co., Ltd.
No. 488, Lunmei Road, Changhua City, Changhua County 500, Taiwan (R.O.C.)

(Manufacturer's name/ Registered address)

Jim Liu / General Manager	劉世偉 Jim Liu	*February 25, 2025*
(Name/Function)	(Legal Signature)	(Date of issue)

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