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	*Y. Sung Handelsvertretung* *Duesselthaler Str. 24, 40211 Duesseldorf Germany*
Common device name	*Bath Safety Grab Bar*
Product and trade name	*HOMCARE* HOMECARE
UMDNS code	***15852**, Rails*
GMDN code	***35584**, Rail, Hand-Hold, Bath*
Single Registration Number (SRN)	***DIMDI register # 00300747***
Product representative model number designated	*Stainless Steel Foldaway, 309SL;* *Coated Grab Bar, L3016F-PL;* *Chrome Grab Bar, L3116F-FB*
Basic UDI-DI	*Stainless Steel Foldaway, 309SL # **4710701880073*** *Coated Grab Bar, L3016F-PL # **4710701880066*** *Chrome Grab Bar, L3116F-FB # **4710701880059***
Risk class of the device	*Class I*
Common Specification (CS) references	*Stainless Steel Foldaway;* *Coated Grab Bar;* *Chrome Grab Bar*
Intended purpose (GMDN definition)	*A grab bar intended to provide a supportive hand-hold for a person with a disability when raising or lowering themselves or changing their body position while bathing in a bath or bathing facility. It will typically be affixed to or around the bath.*
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:

Y. Sung Handelsvertretung
Duesselthaler Str. 24, 40211 Duesseldorf Germany
(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	劉世傑 Jim Liu	*February 1, 2020*
(Name/Function)	(Legal Signature)	(Date of issue)

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