


EU Declaration of Conformity

The following description for the medical device,

Device information	Description
Registered trade name and address	<i>Jan Mao Industries Co., Ltd Zhixin Road, Xin' an Town Industrial Park, Pingguo City, Baise City, Guangxi Zhuang Autonomous Region, China Tel: +86-776-5688-829</i>
Authorized representative	<i>Y. Sung Handelsvertretung Duesselthaler Str. 24, 40211 Duesseldorf Germany</i>
Common device name	<i>Hygiene Products</i>
Product and trade name	 JMC <small>JAN MAO INDUSTRIES</small>
UMDNS code	<i>10961, Commode Seats 10962, Commodes 10802, Shower Chairs</i>
GMDN code	<i>31057, Basic Toilet Seat 31059, Raised Toilet Seat 35584, Bath Hand Rail</i>
Single Registration Number (SRN)	CN-MF-000012257
Germany BfArM Registration Number	<i>Commode: Form number 00165904 Shower Bench: Form number 00165908</i>
Basic UDI-DI	<i>Raised Toilet Seat: 697032084202101115BE9 Commode: 6970320842021011070D8</i>
Risk class of the device	<i>Class I</i>
Common Specification (CS) references	<i>Raised Toilet Seat w/ Arms; Aluminum Commode; Shower Chair / Bench / Stool; etc. (please refer to Appendix I)</i>
Intended purpose Basic Toilet Seat:	<i>A seat intended to be attached to a toilet bowl or toilet chair to provide conventional position, stability, and/or comfort to a seated occupant while toileting.</i>
Raised Toilet Seat:	<i>A non-powered seat designed to enable a person with a disability to sit on the toilet at an elevation above the conventional range for easier sitting and standing. It may be intended to attach to a standard toilet bowl or may be freestanding; it might also include armrests/bars to assist transfer.</i>

<p>Intended purpose Sitz bath chair:</p>	<p><i>A dedicated device designed to be sat upon by a patient in a powered sitz bath for external hydrotherapy to relieve pain or pruritus and to accelerate the healing of inflamed or traumatized tissues of the perianal and perineal areas. The seat of the device is typically open allowing jets of water to reach the sacral, coccyx, rectum, groin and vaginal areas. The device is also typically designed with a back rest, armrests, and a frame in soft plastic [e.g., polyethylene (PE)] materials to prevent undue pressure to the skin during therapy; it may be adaptable for a person with a disability.</i></p>
<p>Conformity assessment procedure performed and identification of the certificates issued by notified body, if applicable</p>	<p><i>Quality Management System ISO 13485:2016 by NQA ISO 9001:2015 by NQA</i></p>
<p>Name and identification number of the notified body, if applicable</p>	<p><i>ISO 13485, NQA Certificate Number: 45024 ISO 9001, NQA Certificate Number: 45023</i></p>

That is covered by the present declaration is in conformity with the Medical Device **Regulation 2017/745/EU** as amended by **2020/561/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 or international 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
Duesselthaler Str. 24, 40211 Duesseldorf Germany

(Company name / Registered place of business)

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

Jan Mao Industries Co., Ltd.
Zhixin Road, Xin'an Town Industrial Park, Pingguo City, Baise City, Guangxi Zhuang
Autonomous Region, China

(Manufacturer's name/ Registered address)

James Fang / CEO

(Name/Function)

James Fang

(Legal Signature)

December 27, 2021

(Date of issue)

Appendix I

Performance Item #	Description
538	Wall Mounted Shower Seat
538D	Wall-Mounted Steel Shower Seat
538DL	Wall Mounted Shower Seat with Legs, Aluminum
539L	Light weight shower stool (alum.)
539L KD	Light weight shower stool, KD version
544B/AL	Aluminum Shower Chair Kit (Backrest)
536KIT	Component Bath Seat Aluminum Swiveling 710mm Frame Kit
847	Aluminum Folding Commode
BE01 (19677)	shower stool , white
BE02 (19679)	shower stool, white, with armrests
BE03 (19681)	shower stool, white, with armrests /backrest
BE04 (19683)	folding Shower chair, white, w/armrests/backrest
BE05 (19685)	suspended shower stool, white, width adjustable
BE06 (19687)	suspended shower stool, white, with backrest
BE07 (19689)	shower seat, white, wall mounted
BE09 (19691)	rotating bath seat, white, with armrests
BE11 (19697)	shower corner stool, white
JMC-5300KD (09-107-8872)	Toilet Surround Rail Safety Frame
AA1921 (JMC-5420)	Bathtub Grab Rail Deluxe
AA1594	Bath Transfer Bench Home craft
DAYBATBE02	Days Aluminum Shower Stool with arms
DAYBATBE11	Days Aluminum Corner shower stool
DAYBATBE04	Days Aluminum Folding Shower Chair
DAYOTA (AC20)	Days Over Toilet Aid
AUSBAT70496 (AC24)	Auscare Steel shower stool
AUSBAT70495 (AC22)	Auscare Steel shower Chair Fixed Type W/O Seat
08-156-1885 (JMC-5102C)	Home craft shower Transfer Bench
08-156-1893 (JMC-5035)	Home craft shower Chair With Back
08-156-1901 (JMC-5300)	Home craft Toilet Safety Frame
08-161-0823 (JMC-5205HDF)	Heavy Duty Steel Commode Kid
08-161-0831 (JMC-5301A)	New Designed Raised Toilet Seat With Arms