

EC Declaration of Conformity

Manufacturer: H&K International Trade Ltd

Address: 8F, Building 5, Jinhua Wanda Plaza, No.107 Guangnan Road, Jindong District, Jinhua, Zhejiang, China

EU Authorized Representative:

Company: Luxus Lebenswelt GmbH

Address: Kochstr. 1, Willich, 47877, Nordrhein-Westfalen, Germany

DIMDI code: DE/0000047791

Product name: Shower Seat

Model: 10100 JHK-9232B Rotating bath stool with tray UDI 2697400307101

10102 JHK-9232A Rotating bath stool without tray UDI 2697400307102

UMDN code: 10-802

Classification: Class I

Rule: According to Rule 1, Annex VIII, Chapter III of (EU) MDR 2017/745

Conformity assessment route: ANNEX II + ANNEX III + Article 19 of (EU) MDR 2017/745

Intended Purpose: A shower seat is a bath aid for those with limited mobility

We hereby declare that the above-mentioned product meets the provision of the Medical Device Regulation (EU) MDR 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices. The EU declaration of conformity is issued under the sole responsibility of the manufacturer.



Standard Applied:

EN ISO 13485:2016	EN ISO 14971:2012	EN 12182:2012	EN 1985:1998
EN ISO 10993-1:2009/AC:2010	EN ISO 10993-5:2009	ISO 10993-10:2010	BS EN ISO 15223-1:2016

Basic UDI-DI	697400307100E5
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Place, Date of Issue:

Jinhua, 12th July, 2022

金华市汉造贸易有限公司
H&K INTERNATIONAL TRADE LIMITED

The signature is signed on behalf of H&K International Trade Ltd.