



Dublin, 28 February 2025

DECLARATION OF CONFORMITY

Regulation (EU) 2017/745 Of the European Parliament and The Council on Medical Devices (MDR)

It is stated that the below EU Declaration of Conformity is issued under the sole responsibility of:

Legal manufacturer: LM Global Design Limited

with registered place of business in:

Suite 123, The Capel Building, Mary's Abbey, Dublin 7 D07 VY68, Ireland

SRN: IE-MF-000046744

As a legal manufacturer **LM Global Design Limited** hereby declare under our sole responsibility, that the medical device listed below with related accessories conform with the relevant provision of Medical Devices regulation 2017/745. Each of the CE marked products listed below have been verified against defined criteria and found to be in compliance with the General Safety and Performance Requirements of Appendix I of the Medical Device Regulation 2017/745, prior to being placed on the market.

The product specified below is a "Technical aid for the disabled", classified as Class I, medical device. The classification is based on the requirements of Annex VIII & Rule I, of the MDR. Conformity assessment was carried out according to Art. 52, pt. 7 after drawing up the Technical Documentation in accordance with Annex II and III. The CE mark has been affixed on the product according to Annex V of the MDR.

PRODUCT FAMILY: Folding Bars (FB)
BASIC UDI-DI: 539153269LMFBFV
GMDN: 35585- Toilet Hand rail

PRODUCT LIST:

Product code	Description	UDI-DI/GTIN/EAN
KING-FB70PC-74	FOLDING BAR 70 CM POWDER COATED WHITE GIMA	05391532691640

EMDN CODE: **Y181803**

ACCESSORY LIST:

BASIC UDI-DI: 539154872LMFBHN

KING-PHPC-KN	PAPER HOLDER FOR FOLDING BAR POWDER COATED	
	WHITE KING	05391548727814

EMDN CODE: Y181899





Intended use:

The Folding Bars allows the user to increase independence and stability during the daily use of the bathroom or the toilet bowl. They work as a robust and safe handle on which the user can hold on to as support. After use the folding bars can be easily put back in vertical position and locked using its safety hook.

Year of first market distribution: 2021

Following harmonized norms and/or common specifications were used for conformity evaluation: BS EN ISO 13485:2016+A11:2021, EN ISO 14971:2019+A11:2021, EN ISO 17966:2016, EN ISO 21856:2022 ISO 14001:2015, PN-EN 1041:2010 + A1 2013, PN-EN 12182:2012.

Luca Mammi, Managing Director LM Global Design Limited

CE