

Dublin, 01 October 2021

DECLARATION OF CONFORMITY
Regulation (EU) 2017/745 Of The European Parliament and of The Council on medical devices (MDR)

We,

LM Global Design Ltd.

with registered place of business in:

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

as a legal manufacturer hereby declare under our sole responsibility, that the medical device listed below with related accessories, meets the essential requirements of Annex I and that it is in conformity with the Regulation (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL on medical devices (MDR).

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, of the MDR.

Conformity assessment was carried out according to Art. 52, pt. 7 and Annex II of the MDR.
The CE mark has been affixed on the product according to Annex V of the MDR.

TRADE NAME: **RTS 15 CM/6IN THUASNE**
ITEM NUMBER: **KING-15-27**
BASIC UDI-DI CODE: **539153269LMRTSKA**
ACCESSORY LIST: **N/A**

Following harmonized norms and/or common specifications were used for conformity evaluation: EN ISO 14971:2019, PN-EN 1041:2010, PN-EN 12182:2012, EN ISO 14001:2015, EN ISO 13485:2016.


Luca Mammi,
Managing Director
LM Global Design Limited

