La Spezia, 26/01/2024

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

We,

K DESIGN SRL

with registered place of business in:

via Vincinella, Loc. Ghiarettolo,
19037 – Santo Stefano di Magra, (SP)
Italy
SRN:

as a legal manufacturer hereby declare under our sole responsibility, that the medical device listed below with related accessories, meets the general safety and performance 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: **BRACCIOLI RIBALTABILI PER ALZAWATER CON FERMO A VITE CENTRALE**
ITEM NUMBER: **ES-11F-KD**
BASIC UDI-DI CODE:
ACCESSORY LIST:

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

K DESIGN S.r.l.
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Roberto Buratta,
Managing Director
K Design SRL

CE

Ref. Declaration of Conformity file ES-11F-KD Rev 00 as of 01/20242