

La Spezia, 2 May 2022

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: ALZA WC H.12 CON VITE E BRACC.RIBAL.KD
ITEM NUMBER: ES-11-12F-KD
BASIC UDI-DI CODE: 803405510LMRTS12G8
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.



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Roberto Buratta,
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