

EC DECLARATION OF CONFORMITY

Manufacturer:

The Helping Hand Company, Bromyard Road, Ledbury, Herefordshire HR8 1NS, UK

EU Authorised Representative:

Sunrise Medical GmbH, Kahlbachring 2-4, Malsch / HD, Baden-Württemberg, 69254, Germany
regulatory@sunrisemedical.de

SRN: GB-MF-000011951

CE Certificate is issued under the sole responsibility of the manufacturer

Product/Range number:

LGA-SB, LGA-SBG, LGA-SG, LGA-SSG
LL2GC-SB, LL2GC-SBG, LL2GC-SSG, LL2GC-TRG, LL2GF-SB, LL2GF-SBG, LL2GF-SSG, LL2GF-TRG
LLAZ-SB, LLAZ-SBG, LLAZ-SSG, LLAZ-TRG, LLAZC-SB, LLAZC-SBG, LLAZC-SSG, LLAZC-TRG, LLAZC-SB, LLAZC-SBG
LLZ-SB, LLZ-SBG, LLZ-SSG
LZ-SB, LZ-SBG, LZ-SG, LZ-SSG, LZE-SB, LZE-SBG

Product Description:

LOWZONE ECO, LOWZONE SWITCH, LOWZONE GEL SWITCH, LOWZONE+, GELZONE, CLIMAZONE, ZIP+

Intended use: To reduce the risk of skin damage caused by pressure through sitting.

Basic UDI number: 5050962CUSHIONS7L

Risk class, if applicable: Class I (Rule 1)

Complies with the requirements of the following Regulations and Standards:

The Helping Hand Company hereby declare that the medical device(s) specified above meet the provision of the Regulation (EU) MDR 2017/745 for medical devices. In accordance with ISO 21856:2022 Assistive products — General requirements and test methods

Also, in Accordance with BS ISO 16840-2:2018-Determination of physical and mechanical characteristics of seat cushions intended to manage tissue integrity.

Also, in Accordance with BS 7176:2007+A1:2011 Specification for resistance to ignition of upholstered furniture -non domestic seating

All supporting documentation is retained at the premises of the manufacturer.

For The Helping Hand Company Limited

Signed:

A blue ink signature of John Walters.

Date:

19-11-24

Name: John Walters

Position: Design & Engineering Manager