



# REHASENSE

## UKCA DECLARATION OF CONFORMITY UK Medical Device Regulations 2002 (UK MDR, S.I. 2022/618), as amended, implementing European Directive 93/42/EEC on medical devices (EU MDD), as they apply in Great Britain

This declaration of conformity is issued under the sole responsibility of Rehasense Sp. z o.o. In compliance with Part II of the UK MDR 2002 (as amended), MDD Annex VII. The undersigned declares that the products listed below meet the relevant Regulation provisions that apply to them and the UKCA Mark may be affixed.

Manufacturer	Rehasense Sp. z o.o. Sulejowska 45G 97-300 Piotrków Trybunalski, Poland
Product name	<b>SPACE LX</b>
Item number	LRaabbUK, LRaabbcc (aa- colour, bbb- size, cc- configuration)
Intended use	The rollator has been designed as a tool to assist walking for people who have mobility problems
Description	four-wheeled support for the disabled, non-sterile, without measuring function
UK product class	I
GMDN code	38702
Basic UDI-DI	59074678ROL6U

Self-assessment by UK Medical Device Regulation 2002 Part II. A notified body was not involved in conformity assessment process.

This present declaration is also in conformity with the following Standards and Regulations:

Standard/ Document Name	Description
Medical Device Regulation 2002	Medical Device Regulation 2002 (UK MDR, S.I. 2022/618) as subsequently amended by the EU Exit Regulations of 2019 (S.I. 2019/791) and 2020 (S.I. 2020/1478)
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
(EU)2017/745 (Article 120)	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017
BS EN ISO 13485:2016+A11:2021	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
BS EN ISO 14971:2019+A11:2021	Medical Devices – Application of Risk Management to Medical Devices
BS EN ISO 20417:2021	Information supplied by the manufacturer of medical device
BS EN ISO 11199-2:2021	Walking aids manipulated by both arms. Requirements and test methods. Rollators.



22-08-2025/ Piotrków Trybunalski/ GEO Roger Spencer Dutton

Rehasense Sp. z o.o.  
Prezes Zarządu

Roger Spencer Dutton



Rehasense Sp. z o.o.  
ul. Sulejowska 45, 97-300 Piotrków Tryb.  
NIP 677-237-14-61, REGON 122658133