## **EU DECLARATION OF CONFORMITY**

- 1. Basic UDI-DI: **2090425RollzFlex2K2**
- 2. Item codes: 3010RF0010, 3010RF0012, 3010RF0013, 3010RF0014, 3011RF0010.
- 3. Name: Rollz International B.V.

Adress: Rotterdamseweg 402M

2629 HH Delft

The Netherlands

4. This declaration of conformity is issued under the sole responsibility of the manufacturer (or installer):

Rollz International B.V.

Rotterdamseweg 402M

2629 HH Delft

The Netherlands

SRN: NL-MF-000002978

5. Rollz Flex rollator.



- 6. The object of the declaration described in point 5 is a **class 1** medical device and is in conformity with **REGULATION (EU) 2017/745 OF THE EURO PEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.**
- 7. References to the relevant harmonised standards used, or references to the specifications in relation to which conformity is declared:
  - NEN-EN 11199-2:2021 Walking aids manipulated by both hands Requirements and test methods Part 2: Rollators.
  - NEN-EN 12182:2012Assistive product for people with disability General requirements and test methods.
  - NEN-EN 1985:1998 Walking aids General requirements and test methods.
  - NEN-EN 14971:2019 Medical devices Application of risk management to medical devices.
- 8. Certified by SGS Taiwan Ltd.

Accreditation No: 1053

Certificate No: HQ60047/2021

9. Signed for and on behalf of

Rollz International B.V.

Delft, 11-10-2021

Martijn Schaaper, CEO Rollz International