EU DECLARATION OF CONFORMITY

1. Basic UDI-DI: 2090425RollzAirL3

 Item codes: 4010RA0010, 4010RA0011, 4011RA0010, 4011RA0011, 4012RA0010, 4012RA0011.

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 Air rollator.
- 6. Intended use: The Rollz Air rollator is a mobility device designed to assist users by providing support and stability during walking and serving as a seating aid for both indoor and outdoor environments.



- 7. 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.**
- 8. 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.
- 9. Certified by SGS Taiwan Ltd.

Accreditation No: 1053

Certificate No:

10. Signed for and on behalf of

Rollz International B.V.

Delft, 30-05-2025

Martijn Schaaper, CEO Rollz International

