## **EU DECLARATION OF CONFORMITY**

1. No. 8718347122225

2. Name:

Rollz International B.V.

Adress:

Treubweb 51

1112BA Diemen

The Netherlands

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

Rollz International B.V.

Treubweb 51

1112BA Diemen

The Netherlands

4. Rollz Motion rollator and wheelchair.



 The object of the declaration described in point 4 is in conformity with REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices.

- 6. References to the relevant harmonised standards used, or references to the specifications in relation to which conformity is declared:
  - NEN-EN 11199-2 Walking aids manipulated by both hands Requirements and test methods - Part 2: Rollators.
  - NEN-EN 12182:1999 Assistive product for people with disability General requirements and test methods.
  - NEN-EN 12183 Manual wheelchairs requirements and test methods.
  - NEN-EN 1985:1998 Walking aids General requirements and test methods.
  - NEN-EN 14971:2001 Medical devices Application of risk management to medical devices.
  - ISO 7176-1:2000 Wheelchairs Determination of static stability.
  - ISO 7176-3:2000 Wheelchairs Determination of effectiveness of brakes.
  - ISO 7176-5:2000 Wheelchairs Determination of overall dimensions, mass and turning space.
  - ISO 7176-7:2000 Wheelchairs Measurement of seating and wheel dimensions.
  - ISO 7176-8:2000 Wheelchairs Requirements and test methods for static impact and fatigue strengths.
  - ISO 7176-16:2000 Wheelchairs Resistance to ignition of upholstered parts –
    Requirements and test methods.
  - ISO 7176-22:2000 Wheelchairs Set-up procedures.
  - NEN-EN-ISO 16840-3:2006 Wheelchair seating part 3: Determination of static impact and repetitive load strengths for postural support devices.
- Certified by TÜV Rheinland Nederland B.V.

Notified Body No: 0336

Certificate No: 11.3065202

Certificate No: 89214773-02

8. Signed for and on behalf of

Rollz International B.V.

Diemen, 31-03-2021

Martijn Schaaper, CEO Rollz International

