

EU DECLARATION OF CONFORMITY

1. Basic UDI-DI: 2090425RollzMotionEZJ
2. Item codes: 2010RE0001
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 Motion Electric rollator and wheelchair.



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 EUROPEAN 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 12182:2012 Assistive product for people with disability – General requirements and test methods.**
- **NEN-EN 12183-2020 Manual wheelchairs – 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.**
- **ISO 7176-1:2014 Wheelchairs – Determination of static stability.**
- **ISO 7176-3:2013 Wheelchairs – Determination of effectiveness of brakes.**
- **ISO 7176-5:2008 Wheelchairs – Determination of overall dimensions, mass and turning space.**
- **NEN-ISO 7176-7:1998 en Wheelchairs – Measurement of seating and wheel dimensions.**
- **ISO 7176-8:2014 Wheelchairs – Requirements and test methods for static impact and fatigue strengths.**
- **NEN-ISO 16840-10:2021 - Wheelchair seating - Part 10: Resistance to ignition of postural support devices - Requirements and test method**
- **NEN-ISO 7176-22:2014 en Wheelchairs – Set-up procedures.**
- **NEN-ISO 16840-3:2014(Cor. 2015-09) en - Wheelchair seating – part 3: Determination of static impact and repetitive load strengths for postural support devices.**
- **EN 12184 Electrically powered wheelchairs, scooters and their chargers - Requirements and test methods**
- **IEC 60601-1-2:2014 + IEC 60601-1-2:2015 Power and control systems for electrically powered wheelchairs and scooters — Requirements and test methods**
- **IEC 62133-2:2017 + IEC 62133-2:2017/AMD1:2021 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems**
- **ISO 7176-21:2009 Secondary cells and batteries containing alkaline or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications – Part 2: Lithium systems**
- **ISO 7176-14:2008 Power and control systems for electrically powered wheelchairs and scooters — Requirements and test methods**

8. Certified by TÜV Rheinland Nederland B.V.

Notified Body No: 0336

Certificate No: 11.3065202 (ISO 12183-2:2020)

Certificate No: 89214773-02 (ISO 11199-2:2021)

Certified by SGS

Certificate No: GZES220701318501

Certificate No: MED GZES2207013185ME

Certificate No: GZES220601139313

Certificate No: GZES220701318601

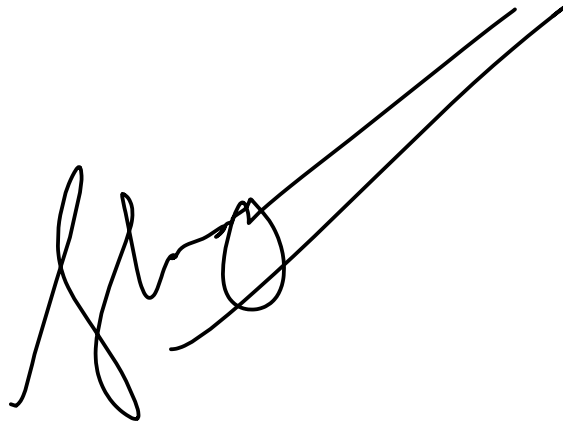
Certificate No: 18270BC20263401

9. Signed for and on behalf of:

Rollz International B.V.

Delft, 25-01-2023

Martijn Schaaper, CEO Rollz International

A handwritten signature in black ink, appearing to be 'M. Schaaper', is written over two parallel diagonal lines that extend from the bottom left towards the top right of the page.