Quha oy
Pirkkalaistie 1
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www.quha.com

CE

EU Declaration of Conformity

Quha oy hereby declares that the product identified herein is a Class I Medical Device and complies with the following EU harmonised legislation:

- Regulation (EU) 2017/745 Medical Device Regulation (MDR)
- Radio Equipment Directive 2014/53/EU
    - Safety &Health (Article 3.1a) EN 62368-1 :2014+A11 :2017, EN 62479:2010
    - EMC (Article 3.1b) EN 301 489-1 V2.1.1, EN 301 489-17 V3.1.1
    - Radio Spectrum Efficiency (Article 3.2) EN 300 328 V2.2.2, EN 300 330 V2.1.1
- IEC 60601-1-2:2014 + A1:2020: Medical electrical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic disturbances – Requirements and tests
- 2011/65/EU Restrictions of Hazardous Substances Directive (RoHS 2)
- REACH and WEEE Directives

Product Information & Use

Type of product: Assistive computer mouse
Product name/model: Quha Zono X
Product description and intended use: The Quha Zono X mouse is intended to be used for computer control for augmentative and alternative communication (AAC) and/or for computer access purposes as an alternative mouse input device for people that have challenges in their ability to access a computer due to injury, disability or illness.
Basic UDI: 643004945QuhaZonoX107W
Single registration number: FI-MF-000004483

I hereby declare that the equipment named above has been designed to comply with the relevant sections of the above referenced specifications. The unit complies with all essential requirements. This EU declaration of conformity is issued under the sole responsibility of Quha oy.

Jan 12th, 2026
Nokia, Finland

Quha oy
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Petri Latva-Rasku, Chairman
Quha oy