

Quha oy Pirkkalaistie 1 37100 Nokia **Finland** www.quha.com

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
 - o Safety & Health (Article 3.1a) EN 62368-1:2014+A11:2017, EN 62479:2010
 - o 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
- 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.

Oct 10th, 2022 Nokia, Finland



Petri Latva-Rasku, Chairman