Medical device

EC DECLARATION OF CONFORMITY

Manufacturer: **OrCam Technologies Ltd.**

CE

Product: **MyEye 2**

We hereby declare, on our own responsibility that our product confirms and meets the safety and performance requirements set out in Annex I of EU MDR 2017/745

Product	Model
OrCam	**MyEye2**

Device Classification

Class I as per Annex VIII of MDR 2017/745

Applied Standards

- EN IEC 60601-1: Medical Electrical Equipment – Part 1: General requirements for Basic Safety and Essential Performance.
- ETSI EN 301 489-1: Electromagnetic compatibility and Radio Spectrum Matters (ERM); Electro Magnetic Compatibility (EMC) standard for radio equipment and services; Part 1: Common technical requirements.
- ETSI EN 301 489-17: Electro Magnetic Compatibility (EMC) standards for radio equipment and services; Part 17: Specific conditions for Broadband data transmission System; Harmonised Standard covering the essential requirements of article 3.1 (b) of Direct 2014/53/EU.
- FCC part 15, Subpart B.
- IEC/EN 60601-1-6: General requirements for basic safety and essential performance- Collateral standard: Usability
- IEC 62366-1:2015: Medical devices- Part 1: Application for usability engineering to medical devices
- EN IEC 60601-1-2: Medical Electrical Equipment – Part 1-2: General requirements for Safety- Collateral Standard: Electromagnetic Compatibility- Requirements and tests.
- EN 62304 Medical device software – Software lifecycle processes.
- RoHS: Restriction of Hazardous Substances DIRECTIVE 2011/65/EU
- WEEE: Waste Electrical and Electronic Equipment Directive.
- EN ISO 14971:2019 Medical devices Application of risk management to medical devices
- Council Directive MDR 2017/745, April 5 2017, pertaining to medical devices.

Regulatory Representative

Arazy Group GmbH

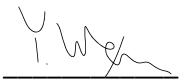
The Squaire 12, Am Flughafen,

Frankfurt am Main, Deutschland

Full Name: Yonatan Wexler

Position: EVP R&D

Date: 01-Oct-2020

Signature: 

Place: Jerusalem

Valid:

Version 2

Product description	**Catalog No.**	**Classification**
Visually impaired aid device	1	1