



Medical device

EC DECLARATION OF CONFORMITY

Manufacturer: OrCam Technologies Ltd.

Address: Kiryat Hamada 3, Jerusalem 9777603 Israel.

Product: OrCam Read

OrCam Technologies Ltd. hereby declares that the above medical devices are in conformity with the applicable requirements of EU MDR 2017/745 as enforced in the national laws of the European Union member states. This declaration of conformity has been issued under the sole responsibility of OrCam Technologies Ltd. as the legal manufacturer of the devices mentioned above.

We hereby declare that our product conforms and meets the safety and performance requirements set out in Annex I of EU MDR 2017/745.

UDI Numbers:

UDI Number	Product Name
7290018906217	ORREAD-0S-AU-01-FEen-MIXX-00
7290018906224	ORREAD-0S-EU-01-NEen-MIXX-00
7290018906231	ORREAD-0S-EU-01-WEen-BSIC-01
7290018906248	ORREAD-0S-EU-01-WEen-BSIC-03
7290018906255	ORREAD-0S-EU-01-WEen-LVLV-01
7290018906262	ORREAD-0S-EU-01-WEen-MIXX-00
7290018906279	ORREAD-0S-EU-01-WEen-SMRT-01
7290018906286	ORREAD-0S-UK-01-WEen-BSIC-01
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7290018906309	ORREAD-0S-UK-01-WEen-SMRT-01
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7290018906323	ORREAD-0S-US-01-AMen-LVBS-01
7290018906330	ORREAD-0S-US-01-AMen-LVSM-01
7290018906347	ORREAD-0S-US-01-AMen-MIXX-00
7290018906354	ORREAD-0S-US-01-AMen-SMRT-01
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7290018906552	ORREAD-0S-EU-01-FEen-SMRT-03
7290018906569	ORREAD-0S-EU-01-FEen-SMRT-04
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7290019853619	ORREAD-BK-EU-1N-MEen-LVLV-03
7290019853800	ORREAD-YL-EU-1N-MEen-SMTA-01
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7290020063014	OREAD5-YL-EU-1N-MEen-SMTA-01
7290020063021	ORREAD-YL-US-1N-AMen-MIXX-00
7290020063144	ORREAD-YL-AU-1N-AMen-SMRT-02
7290020063151	ORREAD-BK-AU-1N-AMen-LVLV-02

Device Classification

Class I as per Annex VIII of MDR 2017/745 according to rule 13

Applied Standards

- EN IEC 60601-1: Medical Electrical Equipment – Part 1: Basic safety and essential performance requirements of medical electrical equipment
 - EN IEC 60601-1-2: Medical Electrical Equipment – Part 1-2: General requirements for SafetyCollateral Standard: Electromagnetic Compatibility- Requirements and tests.
 - IEC/EN 60601-1-6: General requirements for basic safety and essential performanceCollateral standard: Usability
 - 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 62366-1:2015: Medical devices- Part 1: Application for usability engineering to medical devices
 - IEC 60825:2014: Safety of Laser Products Package.
 - IEC 62304:2006, Medical Device Software – Software Life-Cycle Processes.
 - RoHS: Restriction of Hazardous Substances DIRECTIVE 2011/65/EU
 - WEEE: Waste Electrical and Electronic Equipment Directive.
 - ISO 13485:2016 Medical devices — Quality management systems
 - ISO 20417 2021 Medical devices — Information to be supplied by the manufacturer
- Page 3 of 3
- EN ISO 15223-1:2016 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements.
 - EN ISO 14971:2019 Medical devices - Application of risk management to medical devices
 - EU Regulation MDR 2017/745, April 5, 2017, pertaining to medical devices.

Regulatory Representative

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Full Name: Doron Weizman

Position: VP R&D, HW

Date: 05/05/2024

Signature: *Doron Weizman*

Declaration of Conformity OrCam Read 2024

Final Audit Report

2024-05-05

Created:	2024-05-05
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