

ORamaVR SA**Regulatory Positioning Memo — Not a Medical Device***Intended use of ORamaVR products under EU MDR, Swiss MedDO and the US FD&C Act**Document ID: OVR-REG-001 · v1.2***1. Purpose and status**

ORamaVR SA (“ORamaVR”) publishes this memo to state the intended use and regulatory positioning of its products. It is referenced by the Custom SIM Service Agreement (OVR-SVC-001 §2.1 and §11.4), the JARIA Terms of Use (OVR-POL-005 §12) and other suite documents, and is published at oramavr.com/legal/intended-use. It supports customer procurement, regulatory and legal review. It states ORamaVR's own position; it does not create contractual rights beyond the agreements that reference it.

2. Products covered

This memo covers: the VTC Platform (including JARIA in Base and JARIA+ configurations); the SIM Library and the simulations distributed through it (including Publisher-owned SIMs); OMEN, the generative authoring co-pilot; ORamaVR Creator (Pro and Solo) and outputs authored with it; and Custom SIMs produced under OVR-SVC-001, subject to Section 6.

3. Intended use

ORamaVR products are education and training tools for healthcare professionals and healthcare students. They provide XR/VR simulation-based training, procedural rehearsal on virtual anatomy, knowledge support and competency analytics for human review. They are not intended for the diagnosis, treatment, cure, prevention or mitigation of disease or any other medical condition; they are not intended to inform or drive clinical management of any individual patient; and they must not be used as a substitute for professional clinical judgment.

4. Regulatory analysis

4.1 EU MDR. Under Regulation (EU) 2017/745 (MDR), Article 2(1), a “medical device” is an instrument or software intended by the manufacturer to be used for human beings for a specific medical purpose (diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease, among others). ORamaVR's products have no such intended medical purpose: their purpose is the education and training of professionals. Applying MDR Article 2(1) and the MDCG guidance on software qualification, education-and-training software without a medical purpose for an individual patient is not a medical device. ORamaVR products are accordingly not CE-marked as medical devices.

4.2 Switzerland. The same analysis applies under the Swiss Medical Devices Ordinance (MedDO, SR 812.213), which mirrors the MDR definition. ORamaVR products are not medical devices under the MedDO.

4.3 United States. Under Section 201(h) of the US Federal Food, Drug, and Cosmetic Act, a device is an article intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease, or intended to affect the structure or function of the body. ORamaVR products are intended for none of these uses and are therefore not devices under §201(h); they are education and training software consistent with FDA's treatment of tools not intended for clinical use with individual patients.

4.4 AI features. The positioning of ORamaVR's AI features under the EU AI Act — educational/vocational-training use, human oversight of all decisions affecting trainees, and maintained Annex IV-structured documentation — is set out in the AI principles of the JARIA Terms of Use (OVR-

POL-005 §12) and the JARIA Addendum (Annex J to the JARIA Terms of Use, OVR-POL-005), with internal Annex IV documentation maintained as OVR-REF-AI-001.

5. No patient data

ORamaVR products are not intended to process patient-identifiable data. The VTC End-Customer Terms (Exhibit B, OVR-SCH-002 §4) prohibit uploading or processing Patient-Identifiable Data on the platform, and the platform is not offered or configured for the processing of clinical or patient-identifiable health data. Training occurs on virtual anatomy and synthetic scenarios.

6. Customer content and Custom SIMs

6.1 The analysis above depends on intended purpose. Where a customer or partner supplies content, configures a product, or commissions a Custom SIM in a way that gives the result a medical purpose — for example, patient-specific rehearsal intended to inform an actual procedure, or diagnostic decision support — that party becomes responsible for the regulatory qualification, conformity assessment and any required clearances of that use, as its manufacturer or deployer under applicable law.

6.2 Custom SIMs. Under the Custom SIM Service Agreement (OVR-SVC-001), Custom SIMs are produced as education and training tools; the client represents the intended purpose in the SIM Service Order Form, and any intended regulated use must be expressly stated there and separately agreed (OVR-SVC-001 §11.4). The Elite tier's IEC 62304 software-lifecycle integration approach supports clients whose own regulatory posture requires it; it does not, of itself, make a Custom SIM a medical device or ORamaVR its manufacturer.

7. Marketing and claims discipline

ORamaVR personnel and partners must describe the products consistently with this memo: no claims of diagnostic, therapeutic or preventive benefit for patients; no claims that training outcomes substitute for credentialing or clinical judgment; and no use of regulatory terms (CE mark, FDA clearance, medical-device classification) in connection with the products except to state accurately that they are not medical devices. Attribution and brand usage follow OVR-POL-016.

8. Review

Legal/Compliance reviews this memo at least annually and whenever a product change could bear on intended purpose — including new AI features, patient-data-adjacent features, physiological-signal integrations, or any Custom SIM engagement with a stated regulated use — and on material changes to the MDR, MedDO, FD&C Act or related guidance. Questions: legal@oramavr.com.

For information — not legal advice. This memo reflects ORamaVR's positioning as at 16 July 2026 and does not constitute legal or regulatory advice to any recipient; counterparties should take their own advice on their specific use.