# Therapy withVR

## EU AI Act Compliance Statement

| | |
|---|---|
| **Version** | 1.0.0 |
| **Effective date** | 30 days after notice is sent to existing users |
| **Company** | withVR BV |
| **Registered address** | Meulesteedsesteenweg 194 bus 204, Ghent 9000, Belgium |
| **VAT / company number** | BE-0790.909.294 |
| **Governing law** | Belgian law |
| **Jurisdiction** | Courts of Ghent, Belgium |
| **Contact** | hello@withvr.app \| legal@withvr.app |

This document sets out withVR BV's assessment of Therapy withVR's obligations and status under the EU AI Act (Regulation (EU) 2024/1689). It is intended for Data Protection Officers, legal and compliance teams, procurement officers, and institutional users who require documentation of the platform's AI governance position.

This statement covers: the AI features present in Therapy withVR; the risk classification assessment; applicable obligations and their current status; and the obligations that do not apply and why.

## 1. AI Features in Therapy withVR

Therapy withVR includes the following AI-powered features:

| Feature | Detail |
|---|---|
| Avatar voices | All avatar speech inside VR is synthesized using Google Text-to-Speech. Always active in all sessions. The person inside VR hears a synthetic voice, not a human recording. |
| Sentence translation (optional) | Translates conversation text between languages. Uses OpenAI API. Off by default, user-activated. |
| Text generation (optional) | Generates suggested conversation sentences from a topic or prompt. Uses OpenAI API. Off by default, user-activated. |
| Autocorrect (optional) | Corrects spelling and grammar in text entered by the supervising professional. Uses OpenAI API. Off by default, user-activated. |
| Whisper speech recognition (optional) | Converts spoken words to text during session setup. Uses OpenAI API; the recorded audio is sent to OpenAI and is not stored by withVR. Off by default, user-activated. |
| Speaker grammar (optional) | Adjusts gendered grammar to match the avatar's voice. Uses OpenAI API. Off by default, user-activated. |

| | |
|---|---|
| Formality adjustment (optional) | Adjusts formality level of AI-generated text. Uses OpenAI API. Off by default, user-activated. |
| Emotional speech (optional) | Adjusts avatar voice characteristics to match the avatar's set emotion. Uses OpenAI API. Off by default, user-activated. |
| Next question (optional) | With one tap on a quick-response button, generates one new question and the avatar speaks it at once. Uses OpenAI API. Off by default, user-activated. |
| Reading texts (optional) | Generates a short reading passage from a topic, labeled in the Web App as AI-generated text to review before use. Uses OpenAI API. Off by default, user-activated. |
| AI sentence suggestions (optional) | Suggests up to 11 sentences on a topic for a sentence group. The supervising professional approves them before they are saved, and saved suggestions keep an AI mark. Uses OpenAI API. Off by default, user-activated. |
| Starter sentence translation (optional) | Translates withVR's own English starter sentences the first time a situation is opened in a language that does not have them yet. Only withVR's sentences are sent. Uses OpenAI API. Off by default, user-activated: it runs only if the person opening the situation has switched AI on. The result is saved and shared with every account that uses that language, including accounts with AI switched off. |
| Avatar mouth movement in VR | Meta's Oculus Lipsync library turns the avatar's synthesized voice into mouth shapes. Runs on the headset, uses only the avatar's own voice, not a microphone, and the app does not send audio to Meta for it. Always active in the VR App. |

**Important:** All optional features are off by default and must be deliberately activated by the supervising professional. The exception is the starter sentences, which may have been translated by AI for another account. The platform generates scenario content to support communication practice. It does not evaluate, score, diagnose, or make decisions about any person's health, learning, or eligibility for services.

## 2. Risk Classification Assessment

### 2.1 Overall classification: Not a high-risk AI system

Therapy withVR has been assessed against the EU AI Act's risk classification framework and is not classified as a high-risk AI system under Article 6 and Annex III of the Regulation.

**Classification:** Therapy withVR falls within the limited risk category under the EU AI Act, with specific transparency obligations under Article 50 applicable from August 2, 2026. It is not a high-risk AI system. No conformity assessment, EU database registration, or CE marking is required.

**Belgium has not yet designated its market surveillance authority for the AI Act; we will name it here once designated.**

## 2.2 Annex III assessment

Annex III of the EU AI Act lists the categories of AI use cases that are classified as high-risk. The following table sets out each relevant Annex III category and the assessment for Therapy withVR:

| Annex III category | Assessment for Therapy withVR |
|---|---|
| Education and vocational training (Annex III, point 3) - AI that evaluates learning outcomes, monitors and detects prohibited behavior, or determines access to educational institutions | Not applicable. Therapy withVR does not evaluate learning outcomes, monitor student behavior, or determine educational access or placement. The platform provides a virtual speaking environment. All educational and clinical decisions are made by the supervising professional, not by the AI. |
| Healthcare (Annex III, point 5) - AI intended to be used as medical devices, or that assists clinical decision-making in a manner that could harm individuals | Not applicable. Therapy withVR is not a medical device (not CE marked, not FDA regulated). It does not assist clinical decision-making, score assessments, analyze health data, perform patient triage, or influence treatment decisions. The platform creates practice scenarios. Clinical decisions remain with the supervising professional. |
| Employment and workers management (Annex III, point 4) | Not applicable. Therapy withVR is not used for hiring, performance evaluation, or employment management. |
| Law enforcement, migration, justice (Annex III, points 6-8) | Not applicable. |
| Critical infrastructure (Annex III, point 2) | Not applicable. |
| Biometric identification (Annex III, point 1) | Not applicable. No biometric identification is performed. Voice synthesis (Google TTS) generates audio from text - it does not identify or authenticate individuals. |

## 2.3 Article 6(3) exemptions (belt-and-suspenders)

Even if any AI feature in Therapy withVR were considered to touch an Annex III category, the Article 6(3) exemptions would apply. The AI features in Therapy withVR:

- Perform narrow procedural tasks - text generation, translation, grammar adjustment, and voice synthesis
- Improve the outcome of a previously performed human activity - the supervising professional designs and configures the scenario; AI generates supporting content within those parameters
- Are not intended to replace or influence a human assessment without proper human review - all AI-generated content is visible to and controlled by the supervising professional before being presented in VR
- Section 5.2 sets out the optional features whose words are not shown to the supervising professional before the avatar speaks them.

## 2.4 Prohibited practices assessment (Article 5)

Article 5 of the EU AI Act (in force since February 2025) prohibits certain AI practices outright. The following have been reviewed for Therapy withVR:

| Prohibited practice | Assessment |
|---|---|
| Subliminal or manipulative techniques that distort behavior | Not present. Avatar voices and scenario content are fully visible and controlled by the supervising professional. Section 5.2 sets out the optional features whose words are not shown first; the supervising professional decides whether to switch them on. |
| Exploitation of vulnerabilities related to age, disability, or socio-economic status | Not present. The platform supports communication practice. It does not exploit any vulnerability. Users with communication differences interact with it as a practice tool under professional supervision. |
| Social scoring systems | Not present. No scoring, ranking, or profiling of individuals based on social behavior is performed. |
| Real-time remote biometric identification in public spaces | Not present. No biometric identification is performed. |
| Emotion recognition in employment or education contexts | Not present. The platform does not recognize, analyze, or infer emotions from users or participants. |
| AI-generated or manipulated content used to deceive | Not applicable in the platform's context. Avatar voices are disclosed as AI-synthesized (Article 50 disclosure). |

**Conclusion:** No prohibited AI practices under Article 5 have been identified in Therapy withVR.

## 3. Applicable Obligations and Current Status

The following EU AI Act obligations apply to Therapy withVR:

| Obligation | Article | Status | Detail |
|---|---|---|---|
| AI literacy | Article 4 | **In force since February 2025 (amended 2026) - measures in place** | withVR BV takes measures to support AI literacy: it keeps a dated record of the AI training of its founder, who builds and supports the platform; new customers are offered a live onboarding call that covers the AI features, their limits and responsible use; the user guide documents every AI feature. Institutions remain responsible for the AI literacy of their own staff. |
| Prohibited practices review | Article 5 | **In force Feb 2025 - Compliant** | Review completed. No prohibited practices identified. See Section 2.4. |
| Transparency for AI-synthesized voices and AI-generated content | Article 50 | **From Aug 2, 2026 - measures in place from app version 5.0.0** | Disclosure is present in platform documentation, Privacy Policy, EULA, and Terms of Service. From version 5.0.0, both apps show an in-app AI notice (Section 5.1). Earlier versions do not; with them, and inside the VR situations in every version, |

| | | | |
|---|---|---|---|
| | | | supervising professionals inform participants (Section 5.3). |

## 4. Obligations That Do Not Apply

The following EU AI Act obligations apply only to high-risk AI systems and do not apply to Therapy withVR:

| Obligation | Reason it does not apply |
|---|---|
| Conformity assessment (Article 43) | Therapy withVR is not a high-risk AI system under Annex III. |
| Technical documentation under Annex IV | Required only for high-risk AI systems. |
| Quality management system (Article 17) | Required only for high-risk AI system providers. |
| Risk management system (Article 9) | Required only for high-risk AI systems. |
| Data and data governance (Article 10) | Required only for high-risk AI systems that use training data. |
| Logging and record-keeping (Article 12) | Automatic logging requirements apply only to high-risk AI systems. |
| Human oversight measures (Article 14) | Article 14 obligations apply to high-risk AI systems. Human oversight is maintained by design as a clinical best practice, but Article 14 does not impose formal requirements on this platform. |
| Accuracy, robustness, and cybersecurity (Article 15) | Required only for high-risk AI systems. |
| EU database registration (Article 49 / Article 71) | Not required for AI systems outside Annex III scope. |
| CE marking | Not required. Not a high-risk AI system. Not a medical device. |

## 5. Article 50 - Transparency Obligations

Article 50 of the EU AI Act imposes transparency obligations on providers and deployers of certain AI systems. These obligations apply from August 2, 2026. The following Article 50 obligations apply to Therapy withVR:

### 5.1 AI-synthesized voices (Article 50(4))

Article 50(4) requires that persons exposed to AI-generated audio be informed that the content is artificially generated or manipulated. In Therapy withVR, all avatar voices are synthesized using Google Text-to-Speech. The person inside VR hears a synthetic voice in every session.

Disclosure is addressed as follows:

- The supervising professional is informed in the EULA (Section 7), Terms of Service (Section 8), Privacy Policy (Section 4), and this document that avatar voices are AI-synthesized
- The platform documentation states clearly that avatar voices are AI-synthesized using Google Text-to-Speech
- From version 5.0.0, the Web App shows the professional a one-time notice after sign-in saying that avatar voices are computer-generated, that the optional AI features write or change some text, which of that text is marked AI, and which features speak words without showing them first; a standing line on the sign-in screen and in Settings says that avatar voices are computer-generated; the VR App shows "Voices in this experience are generated by AI" on its sign-in screen. There is no label inside the VR situations, so the supervising professional still tells the person inside VR, as the Web App's notice asks. Earlier versions of the apps show no in-app notice
- Supervising professionals are responsible for ensuring that the person inside VR is appropriately informed of AI involvement, as required by their professional obligations and institutional policies

### 5.2 AI-generated text content (Article 50(4))

When optional OpenAI features are activated, some session content (sentences, prompts) may be AI-generated. The supervising professional sees and controls all content before it is presented in VR. Content that originates from AI features is presented to the supervising professional to review, modify, or discard before use.

There is one exception. When next question, sentence translation, autocorrect or speaker grammar is switched on, AI creates or changes the words just before the avatar speaks them, so the supervising professional does not see those words first, and they carry no AI label in the Web App. The supervising professional decides whether to switch these features on, and the spoken sentences are kept in the session record. Starter sentences translated by AI are shown before use but also carry no AI label. From version 5.0.0, the Web App's AI notice tells the professional both (Section 5.1).

Disclosure is addressed in the same documents listed in Section 5.1.

### 5.3 Deployer obligations for institutions

Under Article 50, deployers (institutional users) have their own transparency obligations toward end users. Institutions using Therapy withVR should ensure that:

- Participants are informed that avatar voices are AI-synthesized where required by professional standards, institutional policy, or applicable law
- Any AI-generated scenario content is disclosed to participants where required by informed consent obligations
- Their own AI governance policies covering AI use with clients, students, or research participants are applied

## 6. Third-Party AI Providers and Data

| Provider | Data sent |
|---|---|

| | |
|---|---|
| Google Text-to-Speech | Text strings for voice synthesis only. No personal data about users, clients, or participants in normal operation. |
| OpenAI API | Text entered by the supervising professional into optional AI-powered fields and, for Whisper speech recognition, the audio recorded with it (only when these features are activated). Not client names or participant identifiers. Depending on the feature, this can also include the situation's name, the avatar's earlier sentences, its gender and set emotion and, with speaker grammar or emotional speech switched on, any sentence the avatar is about to say, including saved ones, as written. Under OpenAI's API data usage policy, API inputs are not used to train OpenAI's models by default. |

No client names, session recordings, or personally identifiable information about participants are sent to OpenAI or Google as part of normal platform operation. Supervising professionals are advised not to enter participant identifiers into any AI-powered text field.

## 7. Information for Deploying Institutions

Institutions deploying Therapy withVR in clinical, educational, or research settings should be aware of the following:

| Topic | Detail |
|---|---|
| Classification | Therapy withVR is not a high-risk AI system. Institutions do not have high-risk deployer obligations under Article 26 with respect to this platform. |
| AI literacy (Article 4) | Institutions should take measures to support the AI literacy of their staff who use Therapy withVR (Article 4, in force since February 2025, amended in 2026). withVR BV supports this with a live onboarding call offered to new customers and a user guide that documents every AI feature. |
| Transparency to participants (Article 50) | Institutions are responsible for ensuring that participants are informed of AI involvement where required by professional standards, institutional policy, or applicable law. withVR BV provides disclosure documentation to support this. |
| Professional oversight | All clinical, educational, and research decisions are the sole responsibility of the supervising professional. AI features in Therapy withVR generate supporting content only and do not replace professional judgment. |
| DPIA | A Data Protection Impact Assessment (DPIA) is not required for Therapy withVR on AI Act grounds alone, as the platform is not a high-risk AI system. Whether a DPIA is required under GDPR Article 35 for your specific use case is an institutional determination. withVR BV can provide documentation to support a DPIA on request. |

## 8. EU AI Act Key Dates

| Date | Obligation |
|---|---|
| February 2, 2025 | Article 5 (prohibited practices) and Article 4 (AI literacy) apply |
| August 2, 2026 | Article 50 transparency (informing people they interact with AI; synthetic voices) applies. withVR BV's disclosure obligations under Article 50 apply from this date. |
| December 2, 2026 | Article 50(2) machine-readable marking applies to AI systems placed on the market before August 2, 2026, such as Therapy withVR (Regulation (EU) 2026/1744) |
| December 2, 2027 | High-risk obligations for Annex III uses apply (Regulation (EU) 2026/1744). Not applicable to Therapy withVR; we re-confirm this classification before this date. |
| August 2, 2028 | High-risk obligations for AI in products under Annex I (e.g. medical devices needing a notified body) apply (Regulation (EU) 2026/1744). Not applicable to Therapy withVR. |

## 9. Contact and Further Information

For questions about this compliance statement, to request supporting documentation, or to discuss Therapy withVR's AI governance position:

**withVR BV**
Meulesteedsesteenweg 194 bus 204, Ghent 9000, Belgium
**General enquiries:** hello@withvr.app
**Legal and compliance:** legal@withvr.app