



## ChatMD – Medical Device Terms of Use

These Terms of Use govern access to and use of **ChatMD**, an FDA Class I, 510(k)-Exempt Software as a Medical Device (SaMD). ChatMD provides an AI-assisted, structured symptom-intake interface designed to support users in determining whether telemedicine evaluation through ChatRx may be appropriate.

By using ChatMD, you acknowledge that you have read, understood, and agreed to these Terms. If you do not agree, do not use ChatMD.

### 1. Device Purpose and Intended Use

ChatMD is intended to:

- Collect structured symptom information using an AI-assisted interface
- Assist users in evaluating whether symptoms may qualify for asynchronous telemedicine care
- Provide general informational guidance only

ChatMD **does not**:

- Diagnose medical conditions
- Provide medical advice
- Recommend treatments
- Prescribe medication
- Replace a medical examination or clinical judgment

ChatMD is not intended for use in emergencies or life-threatening situations.

## 2. Regulatory Status and Required Disclosures

ChatMD complies with all FDA General Controls applicable to Class I medical devices.

Regulatory details:

- **FDA Establishment Registration:** 3032847781
- **Owner/Operator Number:** 10091612
- **Device Classification:** Class I, 510(k)-Exempt SaMD
- **Manufacturer:** ChatMD, 328 S. Michigan Street, Plymouth, IN 46563

Regulatory limitations:

- ChatMD has not undergone 510(k) premarket review
- ChatMD is not intended to drive clinical decisions
- No provider-patient relationship is established through ChatMD alone
- ChatMD outputs must not be used as a substitute for professional evaluation

Use of the device constitutes acknowledgment of these regulatory limitations.

## 3. AI Transparency, Performance Limitations, and User Safety

ChatMD uses artificial intelligence to support structured symptom collection.

By using the device, you acknowledge:

- AI outputs may contain inaccuracies, may not recognize all symptoms, and should not be exclusively relied upon
- AI does **not** diagnose, determine medical conditions, or recommend treatment
- Clinical decisions are made exclusively by licensed clinicians through ChatRx Telemedicine or in-person care
- Users should seek medical attention if symptoms worsen or do not improve

ChatMD's AI is continuously refined, but no AI system can guarantee completeness, accuracy, or suitability for all users.

## 4. Not a Substitute for Emergency Care

Do **not** use ChatMD if you are experiencing:

- Trouble breathing or severe shortness of breath
- Chest pain or signs of heart attack
- Sudden confusion, slurred speech, or neurological symptoms
- Severe pain, heavy bleeding, or trauma
- High fever in infants
- Loss of consciousness
- Rapidly worsening symptoms

Call 911 or seek immediate emergency care.

## 5. User Responsibilities

By using ChatMD, you agree to:

- Provide truthful, complete, and accurate symptom information
- Use the device only for lawful purposes
- Use ChatMD only as an informational tool and not as a basis for self-treatment
- Seek clinical care from a licensed healthcare provider when needed
- Not misrepresent your identity, symptoms, or medical history
- Not attempt to interfere with or disrupt ChatMD's operation

Failure to provide accurate information may result in incorrect assessments.

## 6. Device Limitations

ChatMD is not intended for:

- Diagnosis
- Treatment planning
- Chronic disease management
- Mental health assessment
- Pediatric emergency assessment

- High-acuity medical decision-making
- Situations requiring physical examination, diagnostic testing, or imaging

ChatMD should only be used for low-acuity, informational symptom assessment.

## 7. Data Use and Privacy

ChatMD processes information to provide device functionality.

- Information collected through ChatMD may be shared with ChatRx for clinical evaluation only when the user initiates a telemedicine request
- ChatMD operates under federal medical device data-handling expectations and applicable consumer privacy laws
- ChatMD is a HIPAA-covered entity
- Privacy practices are fully described in the **ChatRx & ChatMD Privacy Policy & Consent Notice**

ChatMD does not sell personal or health information.

## 8. No Medical Advice or Clinical Relationship

By using ChatMD, you acknowledge that:

- No provider-patient relationship is formed
- Outputs are generated for informational purposes only
- Only a licensed clinician—not ChatMD—can diagnose, treat, or prescribe
- Medical decisions must not be based solely on ChatMD outputs

## 9. Limitation of Liability

To the fullest extent permitted by law:

- ChatMD is provided “as is” without warranties of accuracy, completeness, safety, or fitness for purpose
- ChatMD and its developers are not liable for harm resulting from reliance on AI-generated outputs

- ChatMD is not responsible for clinical decisions made by independent licensed providers who work for ChatRx Telemedicine
- ChatMD is not liable for missed diagnoses, delays in care, technical failures, or data inaccuracies

## Indemnification

You agree to indemnify and hold harmless ChatMD, its parent company, officers, employees, developers, and affiliates from claims related to your use or misuse of the device.

## 10. Updates and Modifications

ChatMD may update the system or these Terms at any time to maintain regulatory compliance, improve functionality, or support safety. Updates are effective upon posting. Continued use constitutes acceptance of revised terms.

## 11. Governing Law and Arbitration

These Terms are governed by the laws of the State of Indiana.

All disputes will be resolved by **binding arbitration** in Indiana.

Users waive the right to participate in class action or jury trial proceedings.

## 12. Contact Information

For questions or concerns regarding ChatMD:

[trust@chatrx.md](mailto:trust@chatrx.md)

328 S. Michigan Street

Plymouth, IN 46563, United States

~~V0.21925, v1.102225, v1.121125~~

For regulatory inquiries, users may contact:

FDA Center for Devices and Radiological Health (CDRH)

[reglist@cdrh.fda.gov](mailto:reglist@cdrh.fda.gov)

301-796-7400

## 13. Acknowledgment & Agreement

By accessing or using ChatMD, you acknowledge and agree that:

- You have read and accept these Terms
- You understand the device's intended use and limitations
- AI outputs are informational only and do not replace professional medical care
- ChatMD is not a diagnostic, treatment, or prescribing system
- You must seek medical care when advised or when symptoms worsen

If you do not agree to these Terms, you must discontinue use of ChatMD.