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ChatMD – Medical Device Terms of Use

Effective Date: [Insert Date]

1. Introduction

Welcome to **ChatMD**, an **FDA Class I, 510(k)-Exempt** medical device designed to support symptom assessment for select acute infections. ChatMD is an **AI-powered software as a medical device (SaMD)** that provides **informational guidance** based on user-inputted symptoms.

By accessing or using ChatMD, you acknowledge that you have read, understood, and agree to be bound by these **Terms of Use**. If you do not agree to these terms, do not use ChatMD.

2. Device Purpose & Intended Use

ChatMD is intended for **informational and decision-support purposes only**. It provides **AI-driven symptom assessment** for select acute infections based on user input but does **not diagnose, treat, or prescribe medication**.

- ChatMD **does not replace professional medical evaluation** by a licensed healthcare provider.
- It is designed to **assist users in understanding potential conditions** and whether telemedicine consultation or in-person care may be appropriate.
- ChatMD is **not suitable for emergencies** or life-threatening conditions. If you experience severe symptoms, call **911** or seek **immediate medical attention**.

3. Regulatory Compliance & Limitations

ChatMD is a **Class I, 510(k)-Exempt medical device** registered with the **U.S. Food and Drug Administration (FDA)** under the following details:

- **FDA Registration Number:** 3032847781
- **Owner/Operator Number:** 10091612
- **Manufacturer:** ChatMD, 328 S. Michigan Street, Plymouth, IN 46563, United States

Key Regulatory Limitations:

- ChatMD complies with **FDA general controls** applicable to **Class I medical devices**.
- **No doctor-patient relationship** is established by using ChatMD device alone.
- ChatMD **does not provide medical treatment recommendations**—any medical treatment decisions should be made by a licensed healthcare provider.

4. User Responsibilities

By using ChatMD, you agree to:

- **Provide accurate and complete symptom information** to ensure the AI generates the most relevant assessment.
- **Acknowledge that ChatMD's symptom assessment is informational** and should not be the sole basis for medical decisions.
- **Use ChatMD responsibly** and not for unauthorized, fraudulent, or misleading purposes.

Misuse Disclaimer:

- **Failure to provide accurate health information** may lead to **incorrect symptom assessments**.
- Users who misuse the software or **use ChatMD as a substitute for medical care** do so at their own risk.

5. Medical Disclaimer

- **ChatMD does not diagnose, treat, or prescribe medication.**
- The information provided by ChatMD is for **general educational and informational purposes only** and should not be considered medical advice.
- ChatMD **should not replace clinical judgment**—always consult a healthcare provider for diagnosis and treatment.
- If symptoms worsen or new symptoms develop, **seek immediate medical care**.

Not a Substitute for Emergency Care

ChatMD is **not designed for emergency use**. If you experience any of the following symptoms, seek **immediate** in-person medical attention or call **911**:

- ✓ Severe chest pain
- ✓ Shortness of breath or difficulty breathing
- ✓ Sudden confusion, dizziness, or loss of consciousness

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- ✓ Uncontrolled bleeding
- ✓ Severe allergic reactions

6. Liability & Legal Protections

By using ChatMD, you agree that:

- ChatMD and its developers **are not responsible for medical decisions** made based on AI-generated assessments.
- ChatMD **does not guarantee accuracy, completeness, or fitness for a particular medical condition.**
- **ChatMD is not liable for any adverse outcomes** resulting from the use or reliance on its AI-powered assessments.
- ChatMD **does not provide warranties or guarantees** regarding medical advice, treatments, or health outcomes.

Indemnification

You agree to **hold harmless** ChatMD, its parent company, affiliates, officers, employees, and developers from any claims, damages, or losses arising from **your use or misuse of ChatMD.**

7. Governing Law & Dispute Resolution

- These Terms of Use shall be governed by and construed in accordance with the **laws of the United States and the State of Indiana**, without regard to its conflict of law principles.
- Any disputes arising under these Terms of Use shall be **exclusively resolved through binding arbitration** in Indiana, unless otherwise required by law.
- If any provision of these Terms of Use is found to be invalid or unenforceable, the remaining provisions shall remain in full force and effect.

8. Changes to These Terms


ChatMD reserves the right to modify these Terms of Use at any time to ensure ongoing regulatory compliance and service improvements. Any updates will be communicated with an updated **“Effective Date.”** Your continued use of ChatMD constitutes acceptance of any revised terms.

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9. Contact Information


For questions or concerns about these Terms of Use, please contact:

 **Email:** trust@chatrx.md

 **Address:** 328 S. Michigan Street, Plymouth, IN 46563, United States

For regulatory inquiries, contact the **FDA Center for Devices and Radiological Health (CDRH):**

 **Email:** reglist@cdrh.fda.gov

 **Phone:** 301-796-7400 (Option 1)

10. Acknowledgment & Agreement

By using ChatMD, you acknowledge and agree to these Terms of Use, including the disclaimers and limitations of liability outlined above.

◆ **If you do not agree to these terms, you should not use ChatMD.**