



REGULATORY ASSESSMENT: IS ZEBROLD AI MEDICAL DEVICE SOFTWARE?

Working document to be completed with counsel in the European Union and India

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1. Purpose

Software can count as a medical device when its intended purpose is medical, even if no physical device is involved. If Zebrold AI, or any function of it, counts as medical device software, it may need conformity assessment, CE marking and other steps in the European Union, and licensing or registration in India, before it can be used. This document records the facts and the questions that counsel needs to answer.

2. Description of Zebrold AI

Function	Intended purpose (to be completed)	Output used by
Prescription checking	Flags possible dose, frequency, duplicate, interaction and allergy problems	Doctor
Report flagging	Flags results outside reference ranges and unusual combinations	Pathologist or doctor
12-day follow-up	Checks in, reminds and alerts the doctor if symptoms worsen	Patient and doctor
Other functions		

3. Questions for assessment

Question	Answer	Reference
Is the intended purpose to provide information used to make decisions with diagnostic or therapeutic purposes, or to monitor physiological processes?		EU Medical Device Regulation, classification rule for software
Could a wrong or missing output lead to a delay in diagnosis or treatment, or to harm?		Risk analysis
Does the output influence what the doctor prescribes or whether urgent care is advised?		Clinical evaluation
Is the software developed in-house, or supplied by a vendor who is the manufacturer?		Manufacturer duties
Does any function qualify as a high-risk system under the EU rules on artificial intelligence, for example because it is a device that requires third-party conformity assessment?		EU AI Act
Is any function a medical device software under the Indian medical devices rules, and is registration with the central regulator required?		Medical Devices Rules, 2017
Do the Indian and German professional rules on remote care place limits on automated follow-up?		Professional rules

4. Outcome

Jurisdiction	Conclusion	Action required	Owner and date
European Union and Germany			
India			



Until the assessment is signed off, Zebroid AI is used only for the functions described above, under the safeguards in the AI Use Policy (CYD-AI-01), and no marketing claim describes it as diagnosing, treating or preventing any disease.

5. How to reason about classification

The legal question depends on the intended purpose of the software as the company states it, and on what the software actually does, so the description of the functions above must be accurate and complete. In the European Union, software that provides information used to take decisions for diagnosis or treatment, or that monitors physiological processes, is generally treated as a medical device and is classified by the potential harm of a wrong output. Software that only stores, transfers or displays data, or that carries out simple administration, is often outside the rules. In India, the rules on medical devices apply to software that is intended to be used for medical purposes. Counsel should apply the current text of each law and the latest guidance of the regulators.

6. Evidence file to prepare

- A written statement of the intended purpose and the users of each function.
- Design documents, the data used and the way performance was tested.
- A risk analysis that considers wrong, missing and late outputs, and the harm that could follow.
- Clinical evidence that the function is safe and performs as stated, which can include literature and the company's own testing.
- The human oversight and instructions for use given to doctors and patients.
- The vendor's declarations and technical files, where the tool is bought in.

7. Action plan

Action	Owner	Target date
Complete the description of functions and intended purposes	Technical lead	
Obtain written opinions from counsel in the EU and India	Directors	
Decide whether to redesign any function to stay outside the regulated scope, or to seek approval	Directors	
Prepare technical documentation and quality system if required	Technical lead	
Update the AI Use Policy and patient information to match the outcome	AI governance owner	

8. Monitoring after launch

Whatever the outcome, the company monitors how the AI functions perform in use, records problems and complaints, and reports serious incidents to the regulators where the law requires. The assessment is repeated whenever a function changes, whenever a new function is proposed and at least once a year.

9. Scope and assumptions

This assessment covers the functions of Zebroid AI listed above as they exist at the date of the document. It assumes that the AI functions are used only by licensed doctors, pathologists and patients, and that no function gives a diagnosis, chooses a treatment or reduces the review of a doctor. If any of those assumptions changes, the assessment must be repeated before the change goes live.



10. Information needed from the technical team and vendors

- A description of how each function works, the inputs it uses and the outputs it creates.
- The data used to build and test the function, and the results of testing, including error rates.
- The version history, and how changes are controlled.
- The limits of use stated by the vendor, and any regulatory status that the vendor claims.
- The way the function behaves when the data is missing, wrong or unusual.

11. Other laws to consider

Besides medical device rules, the company considers data protection law, rules on telemedicine and on prescribing, consumer protection, rules on advertising of health services and professional rules for doctors. Claims made to patients and partners about Zebroid AI must be accurate and supported by evidence, and must not suggest that the software replaces a doctor.

12. Sign-off

Item	Entry
Prepared by	
Reviewed by counsel (EU and India)	
Approved by directors	
Date and next review	

13. Timeline for the assessment

Stage	Description	Target
1	Complete description of functions and intended purposes	
2	Collect evidence from the technical team and vendors	
3	Obtain opinions from counsel in the EU and India	
4	Decide on redesign, approval or no action	
5	Update policies and sign off	

Approval

This document is approved by the directors of Zebroid Private Limited, the operator of Consult Your Doctor.

Hemendrah Kumar Sadamsetty

Electronically signed | November 5, 2026

Hemendrah Kumar Sadamsetty

Director, Zebroid Private Limited

Date: November 5, 2026

Indu Reddy Morthala

Electronically signed | November 5, 2026

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