AXIOMATIC

Quality and clinical pack

Inora, for quality, the nursing council and the care director

This pack follows the document on Inora and the AI Act, and the supplier file. Where they differ, the articles of the signed agreement prevail.

Version 1.8, 9 November 2026

1. What this pack settles

This pack is for the quality adviser or manager, the nursing advisory council, the care director or elderly-care physician and the head of education of a care organisation that is evaluating Inora. It answers one question: does every answer come from our own protocol? Yes, every answer comes from your own protocol.

The answer in one paragraph. Inora answers from your own organisation's agreements and shows, for every sentence, the source, the version and the passage. If the answer is not in your sources, Inora says so, and where it looked. The professional decides; that intended use is fixed word for word and keeps Inora outside the medical device rules. A document counts in Inora only once it has passed your own route. For every answer Axiomatic records what it rested on, without who asked. When something fails, we investigate the system, never the professional.

2. The intended use

What a system may do follows from its intended use. For Inora it reads, word for word:

> Inora supports professionals with their organisation's knowledge. It answers questions from your sources and shows each of your organisation's sources with one tap, puts what a professional wrote into your report formats and shows what your protocols still ask for. It prepares the follow-up that results, such as the request to the doctor, the list in the record or the check; it goes out only with the professional's approval, and the professional decides.

Inora does not diagnose or decide on treatment (Art. 4.2). Besides: the professional decides and is responsible for the decision; an answer from Inora does not replace the professional's judgement (Art. 4.3).

2.1 Triage

Inora supports triage. The nurse triages, scores and decides. Inora puts the organisation's own protocol beside the nurse, and flags what is missing.

Step	The nurse	Inora
Assess	Sees the client, asks and measures.	Puts your organisation's triage protocol beside the nurse, question by question.
What is missing	Fills in what they don't know yet.	Flags what the protocol still asks for, such as a respiratory rate not yet recorded.
Urgency	Decides how urgent it is.	Never.
Decision	Decides: act themselves, call the doctor or the back-up.	Never.
Record	Reads and signs the report.	Readies it, with the protocol and the version in force; on the nurse's approval it goes into the record.

Inora readies the report; the nurse reads and signs, and only on that approval does Inora file it in the client record; Inora acts on that person's behalf, never with more rights than they have.

2.2 What Inora never does

- It does not diagnose, give a prognosis or decide on treatment.
- It does not assess photos of skin or wounds.
- It does not triage in the nurse's place.
- It does not evaluate staff or take decisions about their work.
- It does not decide whether anyone is eligible for a service.
- It infers no emotion or mood of staff, from voice or face.

3. Where Inora stands in law

Rule	What it says	What it means for Inora
Regulation (EU) 2017/745 (MDR), Art. 2, point 1	Software is a medical device when its manufacturer intends it for a specific medical purpose, such as diagnosis, prediction or treatment.	Inora is not intended for that. Its intended use keeps it outside the medical device rules.
Regulation (EU) 2024/1689 (AI Act), Art. 5(1)(f)	No emotion recognition in the workplace, since 2 February 2025.	Inora infers no emotion or mood.
AI Act, Art. 4	AI literacy, since 2 February 2025, amended as of 27 July 2026 (Regulation (EU) 2026/1744): providers and deployers take measures to support the AI literacy of their staff and of others who work with the system on their behalf. They need not guarantee any specific level for any individual.	We support the AI literacy of whoever works with Inora: what it does, what it never does and how to check a source. We give the training at implementation; your organisation receives the material for its own measures.
AI Act, Art. 50(4)	Published AI text is disclosed, since 2 August 2026.	If an organisation does publish AI text to inform the public on a matter of public interest, it discloses that the text is AI-generated, unless a person has reviewed it and the organisation or a member of staff holds editorial responsibility.
AI Act, Art. 25(1)(c)	Whoever puts a system to a use outside its intended use can become the provider of a high-risk system.	Use Inora within the intended use of section 2.

Inora is not a high-risk AI system: the care professional assesses and decides, and Inora supports them with the organisation's own protocols. With every answer the member of staff sees that Inora drafted it, with its source (transparency, Article 50), and your organisation keeps a record of who was trained to work with Inora (AI literacy, Article 4).

Roles under the AI Act: Axiomatic B.V. is the provider; your organisation is the deployer; the providers of the general-purpose models carry the duties for their models (Art. 53).

Sources: MDR, AI Act, Regulation (EU) 2026/1744.

4. Who answers for what

- **The care provider** answers for good care and for the means it uses for it (Care Quality, Complaints and Disputes Act, Art. 2 and 3). That stays so with Inora.
- **The professional** decides and is responsible for the decision.
- **Axiomatic** answers for what Inora does with your sources; your organisation answers for what your sources say.

5. How an answer is made, and when Inora refuses

Every sentence of an answer rests on a source of your organisation and ends in a mark. One tap on the mark shows the title, the version and the passage the answer comes from. If the answer is not in the sources, Inora says so, shows where it looked and gives no answer from general knowledge. The question goes as a topic, without a name and without the asker's words, to whoever owns the subject.

An example, as the quality page shows it:

	Answered	Not in the sources
Question, 03:12 and 03:40	'I'm alone on the ward tonight and have to give morphine. Who does the double check?'	'She wants to take her own CBD oil alongside the morphine. Is that allowed?'
Inora	The on-call nurse, by video call in the medication administration system. If the nurse doesn't answer within 15 minutes, call the back-up and record that the check was done by phone.	That isn't in your sources, so I won't answer it. What they do say: an over-the-counter remedy alongside prescribed medication only after consulting the pharmacist.
What it rests on	Medication policy MED-04, 4.3, version 7 (adopted 12 June 2026, owner medication committee); Night on-call agreement ORG-12, 2, version 3.	Searched the medication policy (5, Over-the-counter remedies), the formulary 2026 and the pharmacy agreement: no passage. As a topic, without a name, without the asker's words and without the client, to the medication committee.

84% of questions on the inspectorate's risk themes (medication, restraint, wounds, falls and infection) call for the organisation's own protocol. That is why an answer rests on your protocol, not on general knowledge.

6. How a document enters Inora

A document enters Inora the way it enters your handbook.

Role	What it does
The owner	Every document has one at your organisation: a committee, a team or a role. A question without an answer reaches the owner as a topic, without the name or the words of who asked.
Author and content experts	Write and review as in your own document control. Inora changes not a word.
Whoever adopts it	The quality adviser publishes, or the nursing council, as your route prescribes. Only then does a document count in Inora.
Drafts and old versions	Do not count. A replaced version is kept, so you can check what applied on any day.

The life of one document:

Date	Who	What
9 March 2026	A question without an answer	Topic: double check at night, alone on the ward · 2×. Version 6 did not say. Forwarded to the medication committee, without a name and without the care worker’s words.
12 May 2026	Elderly-care physician, author	Writes section 4.3 for version 7.
26 May 2026	Pharmacist and two nurses	Review it as content experts.
12 June 2026	Quality adviser, on the nursing council’s advice	Adopts and publishes it. From that day Inora answers from version 7; version 6 no longer counts.
2 November 2026	An answer to the same question	Rests on 4.3, version 7.

7. Before day one: the intake of your handbook

Every implementation starts with the quality handbook, together with your quality adviser: who owns each document, which version applies and what has expired. You receive the outcome document by document, with the reason. In one quality handbook of 350 documents, 17 subjects were filed more than once, and for 8 of them the versions say different things. Besides that, 21 documents were past their own review date, and some files were stored as images no search can read (export of 24 September 2026, counted by file hash, text comparison and the handbook's own header fields).

What happens to a finding:

What the intake finds	What happens to it
Two versions of one subject	The owner chooses which counts; the other goes.
Review date passed	To the owner, asking whether it still applies.
Stored as an image	Turned into text; the owner approves it before it counts.
A password or personal data in a document	To the owner, never into an answer.

For every source that is not your organisation's own, the licence list states the ground on which Inora uses it.

8. What is on record, and for whom

For every answer Axiomatic records what it rested on: the sources with their versions, the check it passed and the date, and a reference the member of staff sees with the answer. Who asked, the time and the ward are not in it, and the record stays with Axiomatic. On written request, for an incident or a complaint, you receive it.

You request it by date and source, or by that reference, which the nurse can put in their report or incident report themselves. If you ask within the conversation's retention term (90 days by default), we also look up the conversation by the same route and hold it until the investigation closes; after that, only the record remains, which is kept for 2 years. The member of staff is told that their conversation was read.

Field	What it holds
Date	The date of the answer, not the time.

Field	What it holds
Sources	Each document with section, version and adoption date.
Model	The language model the system picked, in the EU, with its version.
Test set	The version of your test set this version of Inora passed.
Reference	The reference the nurse sees with the answer; it does not say who asked.
Not in it	Who asked, the time, the ward, the question and the answer.

The record stays with Axiomatic in Europe (Ireland) and is deleted automatically after that term, from back-ups too within 30 days.

With your organisation: what a worker sends themselves, such as their report or their incident report; topics without an answer, per owner; use per team of at least five people, never per person; the competence record the inspectorate expects (Wkkgz, Wet BIG), as a record of its own with a name, apart from every answer.

Never with your organisation: who asked what; a worker's conversation; a figure or score per person; how often one worker looks something up; a competence derived from a question or an answer. The answer record stays with Axiomatic; you receive it on written request. Axiomatic reads a conversation only on a written request from the function you name for it, for an incident or a complaint; every access is logged and the member of staff is told. In an outage or security incident Axiomatic examines the system logs and the answer record, never a conversation. Whoever made the request gets a finding about Inora, never what the member of staff asked or read. If the law demands a conversation, Axiomatic gives only what the demand asks, logs it, and the member of staff is told, unless the law forbids it.

8.1 The competence record

What a care worker asks Inora never reaches the organisation. Only what the care worker sends reaches it, such as a report or an incident report, and the competence record the inspectorate expects (Wkkgz, Wet BIG). That record sits in Inora Matrix, your competence register for reserved and high-risk procedures under your training policy: the assessor signs off the practical assessment, and from then on it stays current with the procedures the member of staff reports doing themselves, with the protocol and the version that applied. The care worker's questions to Inora never count, not even as evidence of competence. In the pilot it is a preview for the participating team, until the works council consents. It is your own record; Axiomatic keeps it in Inora as processor, on your instruction. It is a record of its own with the worker's name, apart from every answer: Inora never makes it from a question or from the

record of an answer. It records only the procedure, the protocol with its version, the date and on whose instruction, never the content of a conversation, a score or a usage figure. The competence itself you assess, as your training policy prescribes.

Field	Example
Care worker	Sanne de Wit, senior care assistant
Procedure	Subcutaneous insulin injection, a reserved procedure
Protocol	Insulin administration, version 6
Date	14 October 2026
On whose instruction	The client's attending physician

It stays in Inora for as long as the care worker works for you, plus 30 days; in those 30 days you export it to your own personnel file, where your own term applies. Only your team lead and training department see the competence record, and the member of staff themselves. The member of staff sees their own competence record in Inora at any time and receives a copy on request: that is their right of access (article 15 GDPR), which you answer and Axiomatic helps with. Article 5.6 of the data processing agreement„ binds it.

9. The system is at the centre of every investigation

A failure in an answer comes from the system: from a source that is out of date, from a version of the model, from the software around it, from a setting or from our own way of working. That is where we look for the cause, never at the professional who came across the failure. Five steps, every time:

1. **Tell.** We tell whoever the failure affects first; a breach no later than 24 hours after becoming aware.
2. **Restore.** The work goes back to a version that works, the previous one where needed.
3. **Investigate.** Without blame: in the source, the model, the software around it, the configuration and our own way of working. No finding names whoever came across the failure.
4. **Write it down.** What we find, your organisation receives in writing. If the investigation is still running, we add to it.
5. **Change.** The change goes into the system, with a test that keeps the same failure from getting through unnoticed again.

After a calamity Axiomatic delivers a first finding within 5 working days and a report within 4 weeks, inside the eight weeks the inspectorate gives you for your own investigation (Uitvoeringsbesluit Wkkgz, art. 8.7(2)), after your report (Wkkgz, art. 11).

9.1 Your test set, before every new version

We test every new version on your organisation's own questions before your staff work with it: real questions, stripped of the names of clients and staff, only on your written instruction, after the works council's consent where you have one; no person reads them. Every past failure goes into it as a test that stays. If a version does worse than the one before on a single question, it is held back, fixed and tested again.

9.2 Available, day and night

At night too. Your sources stay in your own document system; Inora works with a copy that your handbook manager supplies and keeps up to date. Inora is built for 99.9% availability, with the target of 95% of outages resolved within 4 hours and a response within an hour, day and night.

10. What your organisation does

- Use Inora within the intended use of section 2.
- Name your sources and keep them current. Every document has an owner at your organisation.
- Take measures to support your staff's AI literacy (AI Act, Art. 4, as amended from 27 July 2026). We give the training at implementation.
- Let the professional decide.
- Involve your works council (Works Councils Act, Art. 27(1)(k) and (l)).
- Disclose AI text you publish.
- Report what goes wrong.

11. What you receive from us

Document	When
The intended use, word for word	Before the first question
This quality and clinical pack	Before the first question
The outcome of your handbook intake, document by document with the reason	Before day one
The licence list	Before day one
The AI literacy training material	At implementation
The report of a failure, with the finding and the test	At every incident

Contact: support@axiomatic.digital. Axiomatic B.V., Delft, Chamber of Commerce number 97816825.

12. Inora and the AI Act, in full

This document describes Inora for the AI Act, Regulation (EU) 2024/1689: for the organisations that deploy Inora, their data protection officer, their works council and anyone who supervises them.

About this document

- **System:** Inora
- **Provider:** Axiomatic B.V., Delft, Chamber of Commerce number 97816825
- **Contact:** support@axiomatic.digital

We update this document when Inora, the models it uses or the rules change, and after a serious incident.

Who has which role

- **Provider.** Axiomatic develops Inora and places it on the market under its own name. Under the AI Act we carry the provider's duties.

- **Deployer.** Each organisation that uses Inora under its own authority is a deployer. Its staff work with it.
- **Model providers.** Inora uses general-purpose AI models from other providers. Those providers carry the duties for their models, as Article 53 sets them out.

Inora is not a high-risk AI system: the care professional assesses and decides, and Inora supports with the organisation's own protocols. Inora's intended use falls in no category of Annex III. Annex III, point 5(d), names emergency healthcare patient triage systems; Inora does not triage and sets no priority. The nurse does, and Inora holds the organisation's protocol up beside them.

The duties that do apply, Inora meets: with every answer the member of staff sees that Inora drafted it, with its source (transparency, Article 50), and the organisation keeps a record of who was trained to work with Inora (AI literacy, Article 4).

The intended use

What a system may do follows from its intended use. For Inora it reads, word for word:

> Inora supports professionals with their organisation's knowledge. It answers questions from your sources and shows each of your organisation's sources with one tap, puts what a professional wrote into your report formats and shows what your protocols still ask for. It prepares the follow-up that results, such as the request to the doctor, the list in the record or the check; it goes out only with the professional's approval, and the professional decides.

Inora does not diagnose or decide on treatment. Its intended use keeps Inora outside the scope of the medical device rules.

What Inora never does

- It does not diagnose, give a prognosis or decide on treatment.
- It does not assess photos of skin or wounds.
- It does not triage patients. The nurse triages; Inora supports them with the organisation's own protocol and flags what is missing.

- It does not evaluate staff or take decisions about their work. Figures on use cover only teams of at least five people, never one member of staff, and no one gets a score. The competence record covers only reserved and high-risk procedures under the organisation's training policy; it is the organisation's own, records the procedure, the protocol with its version, the date and on whose instruction, never the content of a conversation, a score or a usage figure, and their questions to Inora never count. The member of staff sees their own competence record in Inora and receives a copy on request (Article 15 GDPR); what that means for the works council is on Works council.
- It does not decide whether anyone is eligible for a service.
- It infers no emotions or mood of staff, from voice or face. Article 5(1)(f) prohibits that.

Whoever puts an AI system to a use outside its intended use can thereby become the provider of a high-risk AI system (Article 25(1)(c)).

Duties that apply now

- **AI literacy** (Article 4, since 2 February 2025, amended from 27 July 2026 by Regulation (EU) 2026/1744). Providers and deployers take measures to support the AI literacy of the people who work with the system on their behalf; they need not guarantee any level for any individual. Whoever works with Inora learns what it does, what it never does and how to check a source. We give the training at implementation, and the organisation receives the material for its own measures. Since the same date emotion recognition at work is prohibited (Article 5(1)(f)); how Inora keeps to that is under What Inora never does.
- **AI text an organisation publishes** (Article 50(4), since 2 August 2026). If an organisation does publish AI text to inform the public on a matter of public interest, it discloses that the text is AI-generated, unless a person has reviewed it and the organisation or a member of staff holds editorial responsibility.

The professional keeps oversight

The professional decides. Inora is built so that they can see what an answer rests on, and contradict it:

- Each of the organisation's sources is marked in the answer. One tap on the mark shows the title, the version and the passage the answer comes from.
- If the answer is not in the sources, Inora says so, and where it looked. The topic goes, without the asker's name or words, to the owner of the source, so the source can be completed.

- In a report, the professional's own words go under the organisation's headings. Inora readies the report; the professional reads and signs, and on that approval Inora files it in the client record; Inora acts on that person's behalf, never with more rights than they have.
- Inora acts only once a person approves.

Where it runs

Inora runs in the EU or on an organisation's own servers. The system picks the language model for each task; who provides it is on Sub-processors. Every new version is tested before staff work with it; on the organisation's written instruction, on its own test set too.

For the team reports the language model that writes the answer sorts the conversation by topic in the same step, in the EU, or on an organisation's own servers inside its network. No person reads along, and the model keeps nothing. The sorting stays in the environment and is deleted with the conversation.

No one trains or fine-tunes a model on an organisation's documents, questions, answers or reports: not us, and not any model provider.

Data	From whom	What for
Sources: documents, protocols, work agreements	The organisation	The answers
Conversations: questions, answers and reports, and the topic of each conversation, without names	The organisation's staff	The conversation itself, and the topic for the team reports, sorted in the same step as the answer; kept 90 days by default. If the organisation asks Axiomatic, within the retention term, to read a conversation for an incident or a complaint, Axiomatic holds it until the investigation is complete and deletes it within 30 days after; the member of staff is told
Answer record: per answer the sources with their versions, the check and the date, and a reference the member of staff sees with the answer; never who asked, the time, the ward, the question or the answer	Axiomatic, of every answer	Accounting for what an answer rested on, for an incident or a complaint; 2 years, at Axiomatic

Data	From whom	What for
Test set: questions from the organisation and flagged answers with their question, stripped of the names of clients and staff	The organisation, only on its written instruction, after the works council's consent where it has one	Testing every new version before it goes live; no person reads a question or answer for it; kept until it withdraws the instruction, at the latest until the end of the agreement, then deleted within 30 days

What we process and why is in the privacy statement.

For organisations that deploy Inora

- **Use Inora within its intended use.** Use it to support triage, never to triage in the professional's place; do not use it to evaluate staff or decide eligibility for services, and do not let it assess photos of skin or wounds.
- **Designate your sources and keep them current.** What Inora says about your organisation rests on the sources you designate. Each document has an owner in your organisation. An outdated protocol gives an outdated answer.
- **Support your staff's AI literacy** (Article 4, as amended by Regulation (EU) 2026/1744). Whoever works with Inora learns what it does, what it never does and how to check a source. We give the training at implementation.
- **Let the professional decide.** Inora supports; the professional takes the decision.
- **Involve your works council.** The works council has a right of consent over a system that processes staff's personal data or can monitor their behaviour or performance (Article 27(1) (k) and (l) of the Dutch Works Councils Act).
- **Disclose AI text you publish,** as set out above under Article 50(4).
- **Report what goes wrong.** If Inora answers wrongly, goes past the line of its intended use, or refuses a question your sources answer, report it to your quality team and to us.

13. The licence list

For every source that is not your organisation's own, it states the basis on which Inora uses it. Inora rests an answer on a national reference only where its publisher allows it. The care worker does not see it: no marker and no link. The record of the answer keeps it. The attribution an open licence asks for appears on a fixed page in Inora's legal notice.