TRANSLATION PENDING NATIVE MEDICAL REVIEWER VALIDATION

IFU v2.0 | Application Ainoha v1.0.0 | Ainoha SAS

INSTRUCTIONS FOR USE

Instructions for Use

Article 23 and Annex I — Regulation (EU) 2017/745 (MDR)

Ainoha Application v1.0.0 — Ainoha SAS

Device	Ainoha Application v1.0.0
Manufacturer	Ainoha SAS
Address	25 rue Beethoven, 38400 Saint-Martin-d'Hères, France
SRN EUDAMED	FR-MF-000053559
Basic UDI-DI	377004258800AINOHAAPPME
UDI-DI	(01) 03770042588008
UDI-PI	(11) 1.0.0
EMDN	V92 — Medical Device Software Not Included in Other Classes
MDR Classification	Class I — Rule 11(c), MDR Annex VIII
Conformity assessment procedure	Self-certification (MDR Annex IV)
Document	Instructions for Use (IFU) v2.0
Previous version	v1.0 of 27 March 2026
Publication date	23 April 2026
Author	Romain Schneeweis — Founder & CEO, PRRC Ainoha SAS

IMPORTANT WARNING

The user must read these instructions before any use of the device. The Ainoha Application is a Class I medical device intended for personal monitoring. It does not replace medical advice, diagnosis or consultation with a healthcare professional. In case of medical emergency, dial 112 (European emergency number).

Document available in the 10 official languages of the marketing Member States: French, German, Italian, Spanish, Polish, Portuguese, Romanian, Bulgarian, Lithuanian, Finnish.

Version history

Version	Date	Changes
v1.0	27 March 2026	Initial version of the IFU.
v2.0	23 April 2026	Comprehensive review as part of the V2 of the technical documentation. Clarification of the MDR Class I — Rule 11(c) classification. Update of references to other V2 documents (CER v2.0, RMF v2.0, GDPR/DPIA Note v1.0, Cybersecurity File v1.0, Vigilance Note v1.0). Confirmation of availability in the 10 official EU marketing languages. Addition of Basic UDI-DI and SRN EUDAMED.

1. Device identification

1.1 Name and version

Ainoha Application — version 1.0.0.

1.2 Manufacturer identification

Corporate name	Ainoha SAS
Legal form	Simplified joint-stock company (SAS)
Registered office	25 rue Beethoven, 38400 Saint-Martin-d'Hères, France
SRN EUDAMED	FR-MF-000053559
Email	contact@ainoha.fr
Website	https://ainoha.fr
Person Responsible for Regulatory Compliance (PRRC)	Romain Schneeweis — Founder & CEO
Vigilance correspondent	Designated to ANSM (France) on 23 April 2026

1.3 Regulatory identification

Applicable regulatory framework	Regulation (EU) 2017/745 on medical devices (MDR)
Status	Medical device (MD) — qualified as medical device software (MDSW)
Classification	Class I — Rule 11(c), MDR Annex VIII
Conformity assessment procedure	Self-certification — MDR Annex IV
Basic UDI-DI	377004258800AINOHAAPPME
UDI-DI	(01) 03770042588008
UDI-PI	(11) 1.0.0
EMDN	V92 — Medical Device Software Not Included in Other Classes
EUDAMED registration	Actor + Device — submitted on 23 April 2026

1.4 CE marking

The Ainoha Application bears the CE marking in accordance with Article 20 of Regulation (EU) 2017/745. The CE marking is digitally affixed and visible on the store listing (App Store and Google Play), on the “About” screen of the Application and in these instructions.

1.5 Marketing countries

The Ainoha Application v1.0.0 is marketed in the following 10 European Union Member States:

- France (FR)
- Germany (DE)
- Italy (IT)
- Spain (ES)
- Poland (PL)
- Portugal (PT)
- Romania (RO)
- Bulgaria (BG)
- Lithuania (LT)
- Finland (FI)

These instructions are available in the official languages of each of these Member States in accordance with Article 10(11) MDR.

2. Intended purpose and exclusions

2.1 Intended Purpose

The Ainoha Application is a personal monitoring software intended for adult women (aged 18 and over) in a perimenopause period who wish to track the evolution of their symptoms on a personal basis, access general educational information about this life transition and receive occasional feedback on their general well-being.

2.2 Target population

- Adult women aged 18 and over
- Living or projecting themselves in a perimenopause period (hormonal transition preceding menopause)
- With no restriction regarding a particular medical condition
- Equipped with a compatible mobile device (cf. §3.2)

2.3 Intended user

The intended user is the end user of the device. No medical training is required. The use is personal, autonomous and outside any clinical context. The Ainoha Application is not intended to be used by a healthcare professional for the care of a patient.

2.4 Explicit exclusions

The Ainoha Application is NOT intended to: diagnose a disease, prevent a disease, monitor a disease in a medical sense, predict or prognose a clinical evolution, treat a disease, compensate for a disability, provide clinical decision support to healthcare professionals or

users, replace medical advice or consultation with a healthcare professional.

The Ainoha Application provides no numerical value of any physiological parameter. The face scan provides exclusively a strictly binary indicator of general well-being. No value of heart rate, respiratory rate, heart rate variability, stress level or blood pressure is displayed to the user.

2.5 Contraindications

To date, no absolute contraindication has been identified. The following conditions of unrecommended use apply:

- Use is not recommended in a medical emergency situation. In such a case, the user must immediately dial 112 (European emergency number) or consult a healthcare professional
- Use of the face scan requires sufficient lighting conditions. It is not recommended in very low lighting or in the presence of significant movements during the scan
- A user presenting an acute medical condition must consult a healthcare professional as a priority — the Ainoha Application does not replace this consultation

3. Description and functionalities

3.1 General description

The Ainoha Application is standalone software (Standalone Software) distributed through the official platforms App Store (Apple Inc.) and Google Play (Google LLC). It runs locally on the user's mobile device and communicates with a server infrastructure operated by Ainoha SAS, hosted on Amazon Web Services (region eu-central-1 — Frankfurt, Germany — datacenter certified HDS “Hébergeur de Données de Santé”).

3.2 Technical requirements

The use of the Ainoha Application requires:

iOS operating system	iOS 15.0 or later
Android operating system	Android 10.0 (API level 29) or later
Front camera	Required for the face scan functionality. Recommended minimum resolution: 720p
Internet connection	Recommended for data synchronisation and access to educational content and the Aino assistant
Lighting conditions (face scan)	Sufficient and uniform lighting. Stable face in front of the camera throughout the scan (approximately 30 seconds)

3.3 Functionalities

3.3.1 Symptom tracking

The user can record on a daily basis the symptoms experienced from a predefined list of 50 symptoms associated with perimenopause. This list is clinically grounded on internationally referenced instruments (Menopause Rating Scale, Greene Climacteric Scale, Menopause-Specific Quality of Life Questionnaire) and on the recommendations of the IMS, NAMS and BMS scientific societies. Input is restricted to this predefined list and includes no medical free-text field. The scientific justification of this list is documented in the Clinical Justification 50 symptoms v2.0 (annex to the Clinical Evaluation Report).

3.3.2 Data visualisation

Evolution charts allow the user to visualise her symptoms over different periods (day, week, month). Data may be exported and shared for informational purposes, in particular when preparing a consultation with a healthcare professional.

3.3.3 Face scan — well-being indicator (rPPG)

The user may carry out a face scan by positioning her face in front of the front camera of the device for approximately 30 seconds. Processing is performed locally on the user's device (on-device) via the Shen.AI SDK from Shen AI s.r.o. No image or video sequence is transmitted to Ainoha SAS or to a third party.

The result is displayed in a strictly binary form: “within the usual norm” or “outside the usual norm”. No numerical value of a physiological parameter is displayed to the user. This indicator is general well-being feedback on a personal basis and does not constitute a medical measurement.

3.3.4 Display of Lab results (binary)

Users who have subscribed to the Ainoha Vitamin D & Omega Test kit (marketed by Ainoha Lab SAS, a subsidiary of Ainoha SAS) may visualise the binary status of their biomarkers within the Ainoha Application. The display is strictly binary (status “within norm” / “outside norm”). No numerical value is displayed. The Ainoha Vitamin D & Omega Test kit is a Class A in vitro diagnostic medical device (IVD) falling under Regulation (EU) 2017/746 (IVDR), distributed by Ainoha Lab SAS, distinct from the scope of the Ainoha Application under MDR. The separation between Ainoha SAS (MDR manufacturer of the Application) and Ainoha Lab SAS (IVD distributor of the kit) is documented in the Ainoha/Lab Separation Note v1.0.

3.3.5 Educational content

The Application provides a library of educational content (articles, practical sheets, videos) on perimenopause, covering topics such as nutrition, sleep, sophrology, physical activity, sexuality. This content is intended for general information and does not constitute personalised medical advice.

3.3.6 Aino assistant

Aino is a conversational assistant based on a language model from Mistral AI (Mistral Medium Latest). It provides general information on perimenopause within an assumed wellness framework. Its behaviour is governed by a locked system prompt that excludes personalised medical advice and diagnosis. Aino does not replace medical advice. The detailed framework for using Aino, including its treatment under Regulation (EU) 2024/1689 (AI Act), is documented in the AI Act Note v1.0.

4. Instructions for use

4.1 Download and installation

- The Application can be downloaded free of charge from the App Store (iOS devices) or Google Play (Android devices)
- An internet connection is required for download
- Installation is automatic after download

4.2 First use and account creation

- On first launch, an onboarding screen presents the device's intended purpose, its limits and key warnings
- Account creation is mandatory and is carried out by email with the definition of a strong password
- Informed consent for the processing of personal health data (GDPR Art. 9) is requested explicitly

- The user may consult the Privacy Policy and the General Terms and Conditions of Use before finalising her registration

4.3 Daily use

Typical use of the Ainoha Application consists of:

- Daily input of symptoms experienced from the predefined list of 50 symptoms, with indication of intensity
- Consultation of evolution charts to follow the evolution over time
- Consultation of educational content according to areas of interest
- Occasional use of the face scan for general well-being feedback
- Occasional exchanges with the Aino assistant for general questions about perimenopause

4.4 Logout and account deletion

- Logout is accessible at any time from the Settings menu of the Application
- Account deletion is accessible from the menu Settings > Privacy > Delete my account
- Deletion of the account triggers the definitive deletion of all associated personal data within a maximum of 30 days

5. Warnings and precautions

This section groups the warnings and precautions that are mandatory in accordance with Article 23 and Annex I MDR. Careful reading of this section is mandatory before any use.

5.1 Main warning — non-medical use

The Ainoha Application is a personal monitoring device with a non-diagnostic and non-therapeutic intended purpose. Under no circumstances does it replace the advice of a healthcare professional. In case of unusual, persistent or worsening symptoms, the user must consult a doctor. In case of medical emergency, dial 112 (European emergency number).

5.2 Face scan warning

The result of the face scan is a general well-being indicator on a personal basis. It constitutes neither a medical diagnosis nor a clinical measurement. No medical decision should be based on this result. In case of doubt about her health, the user must consult a healthcare professional.

5.3 Aino assistant warning

The Aino assistant provides general information on perimenopause for informational purposes. It does not provide a diagnosis, does not prescribe treatment and does not replace medical advice. The information provided by Aino must be considered as guidance elements and not as personalised medical advice.

5.4 Data sharing warning

The data entered into the Ainoha Application are personal health data within the meaning of Article 9 GDPR. Their sharing with third parties (healthcare professionals, relatives, etc.) is the sole responsibility of the user. Ainoha SAS does not share any data with third parties for commercial purposes (cf. §6).

5.5 Use precautions

- Carry out the face scan in sufficient and stable lighting conditions
- Keep the face stable and in front of the camera throughout the scan
- Do not use the Application in a medical emergency situation
- Do not consider the Application as an alternative to a medical consultation in case of worrying symptoms
- Keep the Application up to date by downloading updates offered through the stores
- Use a strong password and activate the screen lock of the device
- Keep the operating system of the device up to date

5.6 Foreseeable misuse

In accordance with the IEC 62366-1 guideline, the following foreseeable misuses have been identified in the suitability for use analysis (Usability Engineering File v1.0 of Ainoha SAS) and must be avoided:

- Considering the binary face scan indicator as a medical result
- Postponing a medical consultation based on use of the Application
- Considering Aino's responses as personalised medical advice
- Using the Application as a self-diagnostic aid
- Sharing the account with a third party (the Application is intended for individual use)

6. Personal data and privacy protection

The processing of personal data within the Ainoha Application is carried out in accordance with Regulation (EU) 2016/679 (GDPR) and the amended French Loi Informatique et Libertés. The details of the data protection arrangements are documented in the GDPR/DPIA Note v1.0 (data protection impact assessment carried out in accordance with Article 35 GDPR).

6.1 Controller

Ainoha SAS, acting as controller within the meaning of Article 4(7) GDPR.

6.2 Categories of data processed

- Identification data: email, first name (optional), date of birth
- Health data (Article 9 GDPR): symptoms entered, intensity, dates
- Technical data: operating system version, device model (anonymised), usage metrics
- Conversations with the Aino assistant
- Binary results of the face scan (image processing being strictly local on the device — no image leaves the device)

6.3 Legal bases

- Explicit consent (Article 9(2)(a) GDPR) for the processing of health data
- Performance of the contract (Article 6(1)(b) GDPR) for the provision of the service
- Legitimate interest (Article 6(1)(f) GDPR) for anonymised usage statistics and improvement of the service
- Legal obligation (Article 6(1)(c) GDPR) for the retention of vigilance and post-market surveillance elements

6.4 Hosting

All user data is hosted on Amazon Web Services (AWS), region eu-central-1 (Frankfurt, Germany), datacenter certified HDS (Hébergeur de Données de Santé). No data is transferred outside the European Union.

6.5 Retention periods

- Active account data: retained as long as the account is active
- Inactive account: automatic deletion after 36 months of inactivity (with prior notification of the user)
- Account deletion at the user's initiative: definitive deletion within 30 days
- Retention for vigilance purposes: in accordance with applicable legal periods (Article 10(8) MDR)

6.6 User rights

In accordance with Articles 12-23 GDPR, the user has the following rights over her personal data:

- Right of access (Article 15 GDPR)
- Right to rectification (Article 16 GDPR)
- Right to erasure (Article 17 GDPR)
- Right to restriction of processing (Article 18 GDPR)
- Right to portability (Article 20 GDPR)
- Right to object (Article 21 GDPR)
- Right to withdraw consent at any time (Article 7(3) GDPR)
- Right to lodge a complaint with a supervisory authority (CNIL in France for French users, national supervisory authority for other EU countries)

To exercise these rights, the user may contact Ainoha SAS at the address: privacy@ainoha.fr. A reply is provided within a maximum of one month (Article 12(3) GDPR).

6.7 Data Protection Officer (DPO)

The appointment of an external Data Protection Officer is in progress and will be effective by 30 September 2026 at the latest (action CAPA-010 of the V2 technical documentation of Ainoha SAS). The contact details of the DPO will be communicated on that date through an update of the Privacy Policy accessible in the Application and on ainoha.fr.

7. Security and cybersecurity

The security of the device and the protection against unauthorised access are ensured by a set of technical and organisational measures documented in the Cybersecurity File v1.0 of Ainoha SAS (consistency with MDCG 2019-16 rev.1, IEC 81001-5-1, MDR Annex I §17).

7.1 Main technical measures

- Mandatory authentication by email and strong password (minimum length 12 characters with complexity rules)
- Encryption of data in transit through TLS 1.2 or higher
- Encryption of data at rest through AWS Key Management Service (KMS)
- On-device local processing of the face scan — no image leaves the device
- Access management according to the principle of least privilege (IAM AWS)
- Continuous monitoring of event logs (CloudWatch)
- Regular database backups
- Vulnerability management and patching policy

7.2 Recommendations to the user

- Choose a strong and unique password (not used on other services)
- Do not share identification data with a third party
- Activate the screen lock of the device (PIN code, pattern, biometrics)
- Keep the operating system and applications up to date
- Do not use the Application on a shared device without locking
- Log out or delete the Application in case of transfer of the device to a third party

7.3 Coordinated Vulnerability Disclosure (CVD) policy

Ainoha SAS implements a Coordinated Vulnerability Disclosure (CVD) policy publicly accessible on the ainoha.fr website. Any vulnerability identified by a security researcher or a user may be reported at the address security@ainoha.fr. Ainoha SAS undertakes to acknowledge receipt within 48 working hours and to handle the report within the timeframes documented in the CVD policy.

8. Incident reporting and vigilance

8.1 Definition of an incident

Within the meaning of Article 2(64) MDR, an incident means any malfunction or alteration of the characteristics or performance of the device, as well as any inadequacy in labelling or in the instructions for use likely to entail a risk to health.

8.2 Reporting procedures to Ainoha SAS

Any user who notices an incident, malfunction, inadequacy or any unfavourable event likely to be linked to the use of the Ainoha Application is invited to report it to Ainoha SAS by the following means:

- Email: contact@ainoha.fr
- “Report a problem” button accessible in the Application (Settings > Help > Report a problem) — implementation planned for 31 July 2026
- Postal mail: Ainoha SAS, 25 rue Beethoven, 38400 Saint-Martin-d'Hères, France

Ainoha SAS undertakes to acknowledge receipt of the report within 48 working hours and to handle the report within the applicable regulatory timeframes.

8.3 Reporting procedures to the competent authority

The user has the option to report any serious incident directly to the competent authority of her country of residence. For French users, the competent authority is the Agence nationale de sécurité du médicament et des produits de santé (ANSM).

Contact details of the competent authorities by country:

Country	Competent authority	Website
Bulgaria	BDA — Bulgarian Drug Agency	https://www.bda.bg
Germany	BfArM — Bundesinstitut für Arzneimittel und Medizinprodukte	https://www.bfarm.de
Spain	AEMPS — Agencia Española de Medicamentos y Productos Sanitarios	https://www.aemps.gob.es
Finland	Fimea — Finnish Medicines Agency	https://www.fimea.fi
France	ANSM — Agence nationale de sécurité du médicament et des produits de santé	https://ansm.sante.fr
Italy	Ministero della Salute	https://www.salute.gov.it
Lithuania	VVKT — Valstybinė vaistų kontrolės tarnyba	https://www.vvkt.lt
Poland	URPL — Urząd Rejestracji Produktów Leczniczych	https://www.urpl.gov.pl
Portugal	INFARMED — Autoridade Nacional do Medicamento e Produtos de Saúde	https://www.infarmed.pt
Romania	ANMDMR — Agenția Națională a Medicamentului și a Dispozitivelor Medicale	https://anm.ro

9. Manufacturer contact

Corporate name	Ainoha SAS
Postal address	25 rue Beethoven, 38400 Saint-Martin-d'Hères, France
SRN EUDAMED	FR-MF-000053559
Website	https://ainoha.fr
General email	contact@ainoha.fr
Privacy and GDPR email	privacy@ainoha.fr
Cybersecurity (CVD) email	security@ainoha.fr
Person Responsible for Regulatory Compliance (PRRC)	Romain Schneeweis — Founder & CEO
ANSM vigilance correspondent	Designated — contact details available from the PRRC

10. Symbols used

In accordance with the standard ISO 15223-1:2021 (Symbols to be used with medical device labels, labelling and information to be supplied):

MD	Medical Device
CE	CE marking — conformity with the essential requirements of Regulation (EU) 2017/745
UDI	Unique Device Identification
Manufacturer symbol	Symbol indicating the manufacturer of the device (ISO 15223-1, symbol 5.1.1)

Instructions symbol	Consult the instructions for use (ISO 15223-1, symbol 5.4.3)

11. Articulation with the technical documentation

These instructions form part of the technical documentation of the Ainoha Application v1.0.0 device in accordance with MDR Annex II. The following documents of the V2 technical documentation of Ainoha SAS are referenced:

MDR Qualification and Classification Note v1.0	§1.3 — MDSW Class I — Rule 11(c) status
CER v2.0 — Clinical Evaluation Report	§2.1 — Intended Purpose. §3 — Description and functionalities. Five performances P1-P5 documented in the CER.
Clinical Justification 50 symptoms v2.0	§3.3.1 — List of 50 symptoms and their clinical grounding
RMF v2.0 — Risk Management File	§5 — Warnings and precautions identified on the basis of the analysis of 53 risks
UEF v1.0 — Usability Engineering File	§5.6 — Foreseeable misuses (UE1-UE12)
GDPR/DPIA Note v1.0	§6 — Personal data and privacy protection
Cybersecurity File v1.0	§7 — Security and cybersecurity
Vigilance Note v1.0	§8 — Incident reporting
AI Act Note v1.0	§3.3.6 — Framework of the Aino assistant
Shen.AI Integration Note v1.0	§3.3.3 — Integration and operation of the rPPG face scan
Ainoha/Lab Separation Note v1.0	§3.3.4 — Ainoha SAS / Ainoha Lab SAS scope
EGSPR v2.0 — Essential Requirements Summary	Consistency with §23.4 (a)-(z) of MDR Annex I documented in the EGSPR

12. Regulatory references

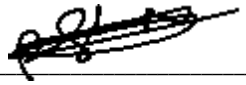
- Regulation (EU) 2017/745 of 5 April 2017 on medical devices (MDR) — in particular Article 10, Article 23, Annex I, Annex IV, Annex VIII
- Regulation (EU) 2017/746 of 5 April 2017 on in vitro diagnostic medical devices (IVDR) — applicable to the Ainoha Vitamin D & Omega Test kit (cf. §3.3.4)
- Regulation (EU) 2016/679 of 27 April 2016 on the protection of natural persons with regard to the processing of personal data (GDPR)
- Regulation (EU) 2024/1689 of 13 June 2024 laying down harmonised rules on artificial intelligence (AI Act)
- MDCG 2019-11 rev.1 — Qualification and classification of software
- MDCG 2019-16 rev.1 — Guidance on Cybersecurity for medical devices
- MDCG 2020-1 rev.1 — Clinical evaluation of medical device software
- MDCG 2020-7 — Post-Market Clinical Follow-up Plan template
- ISO 14971:2019 — Application of risk management to medical devices
- ISO 15223-1:2021 — Symbols to be used with medical device labels
- IEC 62304:2015/AMD1:2020 — Medical device software — software life cycle processes
- IEC 62366-1:2015/AMD1:2020 — Application of usability engineering to medical devices

- IEC 81001-5-1:2021 — Health software and health IT systems safety, effectiveness and security

13. Approval

Document	Instructions for Use (IFU) v2.0 — Ainoha Application v1.0.0
Version	2.0 (comprehensive review)
Previous version	v1.0 of 27 March 2026
Publication date	23 April 2026
Author	Romain Schneeweis — Founder & CEO, PRRC Ainoha SAS
Available languages	FR (reference), DE, IT, ES, PL, PT, RO, BG, LT, FI
Distribution method	Integrated in the Ainoha Application (Settings > Help > Instructions for use) and publicly accessible at https://ainoha.fr/ifu
Next review	Update at each MAJOR release of the Application, at each significant regulatory development or at least annually

Signature of the responsible person:



Romain Schneeweis — Founder & CEO, PRRC Ainoha SAS

Date: 23/04/2026

— End of Instructions for Use v2.0 —