Trifork Digital Health
Åboulevarden 13
8000 Aarhus C
Denmark

ATAH

Instructions for use v. 4.1.2

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Device name	ATAH
Trade name	FMB (Fælles Medicin Beslutningsstøtte)
Software version	`4.1.2`
UDI	`(0)5704002040044(8012)4.1.2`
Legal manufacturer	Trifork Digital Health A/S Åboulevarden 13 8000 Aarhus C Danmark
Use restrictions	ATAH is restricted for use by healthcare professionals with the authority to prescribe medication for patients ⚠️
Electronic access	This instructions for use is provided electronically in a PDF format. A paper copy of the instructions for use can be requested for delivery no later than 7 calendar days after placement of the order. Trifork Digital Health A/S has taken care to ensure the accuracy of this document, however Trifork Digital Health A/S assumes no liability for errors and reserves the right to make changes to the instructions for use without further notice For the most recent instructions for use, please always refer to the electronic instructions for use. The electronic instructions for use can be found at *https://wiki.kliniskbeslutningsstøtte.dk*
Support	For support or questions in relation to ATAH, users are engaged to visit page https://wiki.kliniskbeslutningsstøtte.dk and navigate to "Reporting an error" on the front page. Users can also report directly to ✉️ fmb-support@trifork.com[1]

1. mailto:fmb-support@trifork.com

1. Notice for reporting incidents

Dear user,

This notice serves to inform you that in the event of any serious incident related to the use of this device, it is important to report such incidents promptly. A serious incident is defined as any unexpected event or occurrence associated with the use of the device that results in death or serious deterioration in the health of a user, patient or other person, poses a significant risk of death or serious harm to a user, patient or other person, or which causes a significant risk of damage to property, including the device itself. If you are uncertain whether an event qualifies as a serious incident, please report it for further evaluation or contact us directly for further support.

The reporting should be directed to both the manufacturer and the competent authority of the Member State in which you, as the user, and/or the patient, are established. If you are unable to locate the contact information for the competent authority, we kindly request you to contact our customer support for assistance. The device is currently only for use in Denmark, and in this Member State, the competent authority is Lægemiddelstyrelsen (the Danish Medicines Agency). Your cooperation in reporting incidents is essential for maintaining the highest standards of safety and quality. We appreciate your commitment to the safe use of our product.

For reporting of serious incidents to the manufacturer, please contact us directly via e-mail, fmb-support@trifork.com[2].

Thank you for your attention to this matter.

Sincerely,

Trifork Digital Health A/S

This notice was last updated 2025-09-17

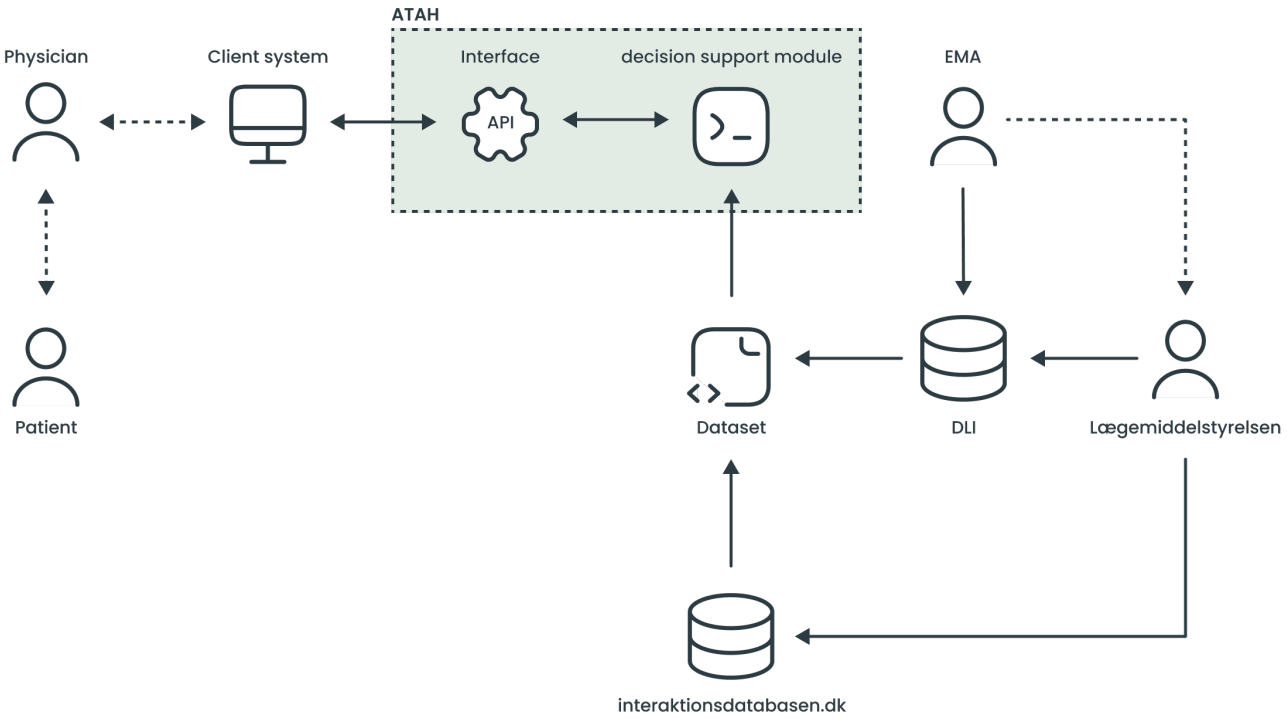
2. mailto:fmb-support@trifork.com

2. Medical device 'ATAH'

2.1 Device description

ATAH, also referred to as FMB (Fælles Medicin Beslutningsstøtte), is a national solution developed by Trifork Digital Health A/S. ATAH is a decision support system that can provide decision support messages via a user's patient management system. Patient mangement systems include EPJ (Elektronisk Patient Journal) and LPS (Lægepraksissystem). When a user prescribes medication to a patient, ATAH performs a review of the medication against national- and international guidelines and patient conditions, and when relevant, presents warning messages to the user. The review is performed by individual rule-based decision support modules (see section 2.8 Decision support modules). The rules utilise data validated by Lægemiddelstyrelsen (the Danish Medicines Agency) in interaktionsdatabasen (the Interaction Database) and Dansk Lægemiddel Information A/S (DLI) on https://www.pro.medicin.dk. ATAH delivers warning messages to the user utilising the same rules that apply if the medication is reviewed to patient conditions when manually accessing information in the medication's SPC (summary of product characteristics), in the interaction database and on https://www.pro.medicin.dk. SPCs are published by EMA (the European Medicines Agency) and Lægemiddelstyrelsen (the Danish Medicines Agency). In addition to providing warning messages when the user prescribes medication to a patient, ATAH can also be used to review a patient's medication list. This review will list all relevant warning messages and can be performed when a user accesses the patients medication list.

2.2 Device overview



2.3 Intended purpose

The intended purpose of the medical device, ATAH, is to provide client systems with messages based on clinical datasets and patient data. The messages can be used by the general physician as decision support for providing informed prescriptive medication.

2.4 Intended users

The intended users of the medical device, ATAH, are physicians with authority to prescribe medication to patients in Denmark. The device can be used by physicians in the primary sector (general practice) and in the secondary sector (hospitals) when the user's client system (LPS or EPJ) has implemented ATAH.

2.5 Indications for use

ATAH can be used in all situations where a user prescribes- or reviews a medication approved in Denmark. All approved medications are listed by Lægemiddelstyrelsen (the Danish Medicines Agency) on https://medicinpriser.dk/

2.6 Contraindications

No contraindications are identified with the use of ATAH.

2.7 Intended clinical benefit

The use of ATAH is intended to result in an *indirect*[*] clinical benefit to patients, as ATAH is able to assist physicians by conducting a comprehensive analysis of the specific patient's data, and compare it to medicinal-product data, which can then be used as support for decisions regarding a patient's prescriptive medication, either for new medications (prescription) or for review of a patient's existing medications.

[*]The intended clinical benefit of ATAH is *indirect* because,

- ATAH does not directly achieve a positive impact on patients
    - ATAH can only *support* the physician by providing messages
    - The positive impact on patients depend on the *decision* made by the physician
- ATAH enables a procedure to be undertaken and a therapy to be delivered
- ATAH is designed to assist general physicians in making informed decisions
- ATAH uses patient-specific data to provide relevant, accurate and timely messages
- ATAH is dependent on the further therapeutic actions made by the physician

2.8 Principles of operation

When ATAH is implemented in a client system, see section 6) Client systems, users are automatically provided with decision support messages when (1) the user prescribes medication to a patient or (2) reviews a patient's medication list. Decision support messages are displayed to the user at point-of-care

and in the user's client system. The user does not need to perform any actions to access or use the decision support system. Based on the user's actions performed in the client system, ATAH receives requests and provides a response.

ATAH can use the following code systems:

Code	Used for	Reference
ICPC-2	Diagnose (primary care)	WHO ICPC-2[3]
ICD-10	Diagnose (secondary care)	WHO ICD-10[4]
ATC level 3, 4 and 5	Cave (allergy)	Sundhedsdatastyrelsen - Klassifikation af lægemidler[5]
NPU	Lab. measurement	Sundhedsdatastyrelsen - NPI terminologien[6]

3. https://www.who.int/standards/classifications/other-classifications/international-classification-of-primary-care
4. https://www.who.int/standards/classifications/classification-of-diseases
5. https://sundhedsdatastyrelsen.dk/indberetning/klassifikationer/klassifikation-af-laegemidler
6. https://sundhedsdatastyrelsen.dk/indberetning/terminologi/npu

ATAH has the following message types:

Type	Color	Used for
Contraindication	Red	Used for decision support messages of high importance. This severity is for example used by the maximum dose module when a dose exceeds the recommended dose
Caution	Orange / Yellow	Used for decision support messages where the physician should be cautious
Information	*Optional*	Used for other types of decision support, e.g. module R11 Antibiotics that provide a link to an antibiotic guidance on www.pro.medicin.dk[7]
CurrentlyUnderReview	*Optional*	The medication is under review by clinical experts. The review process is controlled by Dansk Lægemiddel Information A/S who assigns review tasks to clinical experts (authors) appointed by the official medical organisations in Denmark
NotIncluded	*Optional*	Used by the maximum dose module (R3) to inform when a patient has a drug with an active ingredient that is not supported. The complete list of active ingredients that are not included for decision support can also be seen on page https://pro.medicin.dk/Specielleemner/Emner/318775#a000
MissingData	*Optional*	Some patient data is missing. Additional patient data can improve the quality of the decision support message (e.g. weight, height)

ATAH also has message sub-types. The sub-types are used for mapping decision support messages, however not visible to the user. Information about sub-types can be found on https://wiki.kliniskbeslutningsstøtte.dk

2.9 Decision support modules

ATAH contains 12 individual modules:

- Module 1 "Drug-drug interactions"

7. http://www.pro.medicin.dk

- Module 2 “Cross reactivity”
- Module 3 “Maximum dose”
- Module 4 “Reduced kidney function”
- Module 5 “Double prescription”
- Module 6 “Children”
- Module 7 “Registered diagnosis”
- Module 8 “Missing indication”
- Module 9 “Pregnancy”
- Module 10 “Breastfeeding”
- Module 11 “Guidelines for antibiotics”
- Module 12 “Drug monitoring”

Module 1 “Drug-drug interactions”	
Module description	Module R1 can provide decision support messages for drug-drug interactions by comparing a patient's current- and new prescriptions with the dataset for drug-drug interactions. The interactions are provided by the Danish Medicines Agency (competent authority in Denmark), manufacturer of https://www.interaktionsdatabasen.dk
Dataset provider	The Danish Medicines Agency
Patient data used	• Current prescriptions • New prescriptions

Module 2 “Cross reactivity”	
Module description	Module R2 can provide decision support messages for drug allergies (Cave) by comparing a patient's current- and new prescriptions with the patient's registered Cave. A Cave can either be for a specific drug (registered by drug id) or for a specific active ingredient (registered by ATC-code). The module provides decision support messages for all direct matches on drug id, direct matches with ATC-code on level 5, and for drugs that are known to cross-react with the drug or active ingredient that the patient has a Cave for
Dataset provider	Dansk Lægemiddel Information A/S (DLI)
Patient data used	• Cave • Current prescriptions • New prescriptions

Module 3 “Maximum dose”	
Module description	Module R3 can provide decision support messages when the maximum dose for an active ingredient is exceeded for the particular patient. The total dose is calculated by adding the doses of an active ingredient across the patient's medication list. The maximum dose can either be; per day(s) or per week(s) dependent on the active ingredient. The module cannot provide decision support on maximum dose for less than 24 hours (e.g. hourly or per minutes)
Dataset provider	Dansk Lægemiddel Information A/S (DLI)
Patient data used	• Age • Current prescriptions • New prescriptions And if available: • Weight • Height • Kidney function (GFR/eGFR)

Module 4 “Reduced kidney function”	
Module description	Module R4 can provide decision support messages for drugs that should be used with caution when a patient has a reduced kidney function. A reduced kidney function is determined by a patient's GFR measurement (GFR < 90) [https://www.kidney.org/atoz/content/gfr]. The module compares a patient's current and new prescriptions with the patient's registered kidney function. If no kidney function is registered for the patient, but a kidney function is relevant to the drug prescribed, the module will provide a decision support message to inform the user that a GFR is relevant to the prescription
Dataset provider	Dansk Lægemiddel Information A/S (DLI)
Patient data used	• Age • Kidney function (GFR/eGFR) • Current prescriptions • New prescriptions And if available: • Weight • Height

Module 5 “Double prescription”	
Module description	Module R5 can provide decision support messages for duplicate prescriptions and other combinations that should be avoided. The module compares the chemical subgroup (ATC-code level 4) for drugs across the patient's medication list with the datasets for duplicate prescriptions and special combinations. For example, one special combination that should be avoided is the concurrent use of an angiotensin converting enzyme (ACE) inhibitor or an angiotensin-II receptor blocker (ARB), with a diuretic and a non-steroidal anti-inflammatory drug (NSAID), also called a *tripple whammy*.
Dataset provider	Dansk Lægemiddel Information A/S (DLI)
Patient data used	• Current prescriptions • New prescriptions

Module 6 “Children”	
Module description	Module R6 can provide decision support messages for drugs that are contraindicated- or should be used with caution for children < 18
Dataset provider	Dansk Lægemiddel Information A/S (DLI)
Patient data used	• Age • Current prescriptions • New prescriptions

Module 7 “Registered diagnosis”	
Module description	Module R7 can provide decision support messages for drugs that are contraindicated- or should be used with caution when compared to a patient's registered diagnosis. If a patient has a diagnosis registered in the EHR system (with ICD-10 or ICPC-2 code), this diagnosis will be compared to the patient's current- and new prescriptions. The module can also provide decision support messages for the lab measurements for potassium (K), sodium (Na) and hemoglobin (Hgb) when the level indicates contraindication- or caution in relation to a current- or new prescription. If the patient has a registered diagnose in relation to K, Na or Hgb, and a more recent measurement indicates normal levels, this measurement will *supress* the decision support message. The levels used for this are national guidelines documented in Lægehåndbogen (https://www.sundhed.dk/sundhedsfaglig/laegehaandbogen/) NB: This module can not diagnose a patient. Lab measurements can be temporarily used by this module to provide decision support.
Dataset provider	Dansk Lægemiddel Information A/S (DLI)
Patient data used	• Registered diagnosis • Laboratory measurements • Current prescriptions • New prescriptions

Module 8 “Missing indication”	
Module description	Module R8 can provide decision support messages for prescriptions that do not contain an indication (reason for prescription). If the user has not entered an indication in a specific prescription, this module will inform the user that an indication for the prescription is missing
Dataset provider	Dansk Lægemiddel Information A/S (DLI)
Patient data used	• Registered diagnosis

Module 9 “Pregnancy”	
Module description	Module R9 can provide decision support messages for drugs that are contraindicated- or should be used with caution when a patient is pregnant. The patient's pregnancy status (true = pregnant, false = not pregnant) is compared to the patient's current- and new prescriptions
Dataset provider	Dansk Lægemiddel Information A/S (DLI)
Patient data used	• Pregnant / not pregnant • Current prescriptions • New prescriptions

Module 10 “Breastfeeding”	
Module description	Module R10 can provide decision support messages for drugs that are contraindicated- or should be used with caution when a patient is breastfeeding (Lactating). The patient's breastfeeding status (true = breastfeeding, false = not breastfeeding) is compared to the patient's current- and new prescriptions
Dataset provider	Dansk Lægemiddel Information A/S (DLI)
Patient data used	• Breastfeeding / not breastfeeding • Current prescriptions • New prescriptions

Module 11 “Guidelines for antibiotics”	
Module description	Module R11 can provide decision support messages when the user prescribes an antibiotic drug to a patient, or an antibiotic drug is present in the patient's medication list. The message contains a direct link to an antibiotic guidance on http://pro.medicin.dk
Dataset provider	Dansk Lægemiddel Information A/S (DLI)
Patient data used	• Registered diagnosis

Module 12 “Drug monitoring”	
Module description	Module R12 can provide decision support messages for drugs that are relevant to monitor in relation to kidney function, age and diagnosis. For example, the module can inform the user that for a specific drug, it is relevant to measure the patient's kidney function again in x amount of months
Dataset provider	N/A - Uses datasets from modules 4, 6 and 7
Patient data used	N/A - See modules 4, 6 and 7

3. Warnings and precautions

Use of the decision support system	ATAH must only be used by physicians who have authority to prescribe medication to patients in Denmark.
Client systems	The client system used within clinic implements ATAH and is responsible for the visual representation of decision support messages. The decision support is automatically provided through the client system, when the user prescribes medication or reviews a patient’s medication list.
Messages are support only	Decision support messages are not to be used as the sole base of clinical decisions. Messages should only be used for support, and should always be used in adjunction to other patient information and clinical guidelines. Users cannot be held accountable for deviating from decision support messages when their medical knowledge and experience justify alternative courses of action.
Quality of messages	The quality of decision support messages depends on the correctness and availability of patient data. ATAH uses patient data on Cave, diagnosis and laboratory measurements. More specific patient data, e.g. on Cave for allergies, will improve the quality of messages. To reduce input errors, the input values are summarised in the decision support message for the user to see.
Datasets	Medication data is validated prior to use in ATAH. The data is provided by Lægemiddelstyrelsen (the Danish Medicines Agency), and Dansk Lægemiddel Information A/S (DLI). Data provided by Lægemiddelstyrelsen is equivalent to data within the Interactiondatabase, and data provided by DLI is equivalent to data found on pro.medicin.dk[8].

8. http://pro.medicin.dk

Risks related to use	Errors in the software, patient data or clinical datasets can results in *missing-*, *incorrect-* or *repetitive* decision support messages. If an error occur, please report the incident to the manufacturer according to the provided guidelines for reporting of feedback, here: https://wiki.kliniskbeslutningsstøtte.dk[9].
Non-registered drugs	The device is capable of providing decision support for non-registered drugs only in relation to cross reactivity and double prescription, as its functionality is limited by the ATC-code. Users should be aware that decision support is constrained to these areas, and other areas of the system may not offer decision support for non-registered drugs.
Prioritisation of diagnosis codes	The system prioritises the ICD-10 code over the ICPC-2 code, if the user provides a diagnose with an ICPC-2E code. This prioritisation ensures that decision support aligns with the most widely recognised classification system, improving the system's utility in clinical settings.

4. Disclaimers

- ATAH is intended to provide decision support and is not to be used as the sole basis for decisions
- ATAH has no responsibility for final decisions taken
- ATAH uses validated information provided by Lægemiddelstyrelsen and DLI
- ATAH provides decision support for client systems with access
- ATAH provides no graphical user interface and has no responsibility for the visual representation of messages

5. User training

No user training is required to use ATAH

ATAH automatically provides messages when the user (1) prescribes medication and (2) reviews a patient's medication list. Users are recommended to read this instructions for use.

6. Client systems

ATAH is implemented in the following systems:

System	Manufacturer
Sundhedsplatformen (SP)	Epic Systems Corporation

9. https://wiki.xn--kliniskbeslutningssttte-4mc.dk/

System	Manufacturer
Midt EPJ / Nord EPJ	Systematic A/S
FMK Online	Trifork Digital Health A/S
XMO	CompuGroup Medical
EG Clinea	EG A/S
MultimedWeb	DataGruppen Multimed A/S
Vena	Vena Aps
Novax A/S	Novax A/S

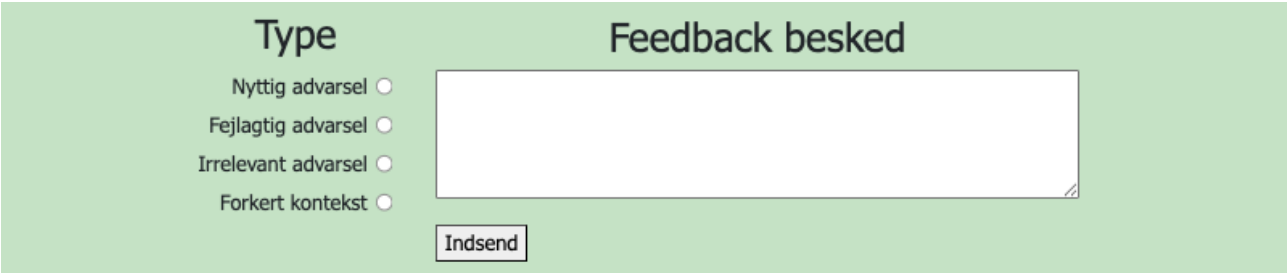
*This instructions for use also applies to users on previous major versions. ATAH migrates a decision support request to the most recent software version, and then migrates the decision support response back to the user's version.

7. Feedback and complaints

Feedback and complaints can be reported using the guideline available on https://wiki.kliniskbeslutningsstøtte.dk[10].

7.1 Feedback functionality

If a client system has implemented the feedback functionality, a link to provide feedback is available inside the decision support message. Feedback provided by the feedback functionality is logged and assessed by Trifork Digital Health A/S. When using this feedback functionality to provide feedback, please select *type* "Nyttig advarsel" (Helpful), "Fejlagtig advarsel" (Error), "Irrelevant advarsel" (Irrelevant) or "Forkert kontekst" (Wrong context) and provide a *comment* in "Feedback besked". Click "Indsend" to send the feedback.



10. https://wiki.xn--kliniskbeslutningssttte-4mc.dk/

The feedback functionality is optional. For guidelines to implementation of the feedback functionality, please consult document "*Installation guideline v. 4.1.1*" available on https://wiki.kliniskbeslutningsstøtte.dk

8. Hardware and software requirements

For hardware and software requirements to implementation of ATAH version 4.1.1, please consult document "*Implementation guideline v. 4.1.1*" available on https://wiki.kliniskbeslutningsstøtte.dk

9. Performance

ATAH has the following performance requirements:

- Uptime/downtime - 99,5% per month
- Response time - p95 = 0,5s (simple) + 1,0s (complex) and p98 = 1,5s (simple) + 3,0 s (complex)

p95 is 95% of all messages, p98 is 98% of all messages
Simple = Patient has < 6 drugs in the medication list
Complex = Patient has > 6 drugs in the medication list

Uptime/downtime can be found on status page: https://fmb.statuspage.io
On this status page it is possible to sign up to notifications

10. Software updates

ATAH uses semantic versioning (x.y.z)

x = major version
y = minor version
z = patch version

Trifork Digital Health A/S notifies Region Nord of a new release within:

Version	Notification	Comments
Patch	14 days	Client systems do not need to modify the existing implementation of ATAH. Patch releases are used for small adjustments and bug fixes. The existing implementation is still supported
Minor	1 month	Client systems can modify the existing implementation of ATAH to include additional functionality. The existing implementation is still supported

Version	Notification	Comments
Major	3 months	Client systems shall implement the new major version of ATAH using the installation guideline provided. The previous major version will continue to be supported until all client systems have implemented the new major version

11. Data privacy

Trifork Digital Health A/S complies with Regulation (EU) 16/679 (General Data Protection Act, GDPR) and protects data privacy with,

- Pseudonymisation of requests
    - All requests are individual and identified with a unique id
- Requests do not directly contain PII (personally identifiable information)
    - Birth date instead of full CPR-number
- Requests are stored in an s3 bucket provided by Amazon Web Services EMEA SARL (AWS Europe)
    - Data warehouse is located in Ireland
    - Data is automatically deleted after 6 months
    - Data is governed by authorisation and authentication

12. Label

12.1 Symbols used

Symbol (ISO 15223-1:2021)	Symbol description
	*Medical device* Name of medical device
	*Model number* Software version
	*Unique device identifier* UDI

Symbol (ISO 15223-1:2021)	Symbol description
	*Manufacturer* Name and address
	*Date of manufacture* Format YYYY-MM-DD (ISO 8601)
	*Consult electronic instructions for use* Website of electronic instructions for use

12.2 Primary label

MD	ATAH
#	`4.1.2`
UDI	`(0)5704002040044(8012)4.1.2`
	Trifork Digital Health A/S Åboulevarden 13 8000 Aarhus C Denmark
	`2025-10-25`
	https://wiki.kliniskbeslutningsstøtte.dk
CE 2797	CE 2797 - Notified body: BSI Group The Netherlands B.V.

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