

REGULATORY PATHWAYS FOR MEDICAL DEVICE SOFTWARE DEVELOPED BY HEALTHCARE INSTITUTIONS

IN-HOUSE EXEMPTION

Christophe Driesmans



TABLE OF CONTENTS

- General aspects
- Conditions of in-house
- Registering in-house device
- Conclusion



IN-HOUSE IN MDR/IVDR?

Catchy shorthand for Article 5(5)

Article 5(5) provides a conditional exemption for devices manufactured and used solely within health institutions under strict criteria.

Allows member states to restrict manufacturer and use of specific types of medical devices

Excludes industrial production



LEGAL FRAMEWORK - EU

European legislation ([MDR](#)/[IVDR](#))

Devices exempted from MDR/IVDR requirements if:

- General Safety and Performance Requirements (Annex I)
- Used and manufactured in a health institution in the EU
- Follow conditions of Article 5(5): 8 (MDR) or 9 (IVDR)
- Not manufactured on an industrial scale



Guidance

[MDCG 2023-1](#) Guidance on the health institution exemption under Article 5(5) of Regulation (EU) 2017/745 and Regulation (EU) 2017/746



LEGAL FRAMEWORK - BE

Belgian legislation

[Law 22/12/2020](#), [RD 12/05/2021](#) (MDR)

[Law 15/06/2022](#), [RD 14/09/2022](#), [RD 25/09/2022](#) (IVDR)

Prohibited:

- Implantable devices
- Devices emitting ionizing radiation

Publication of declaration in FAMHP's web portal -> registration is obliged

Vigilance obligations

[FAMHP website](#), Circulaire 655 ([NL](#)/[FR](#))



MANUFACTURING DEVICE

- Software for data-modification/research/epidemiological studies \neq medical device
- Re-using such software for individual benefit of patient (e.g. treatment, diagnosis) can create a medical device
- Modifying the intended purpose of existing medical device
=> creates new medical device
- In “large” software project: medical device status can be on module/part level



HEALTH INSTITUTION

Definition according to MDR/IVDR

An organisation the primary purpose of which is the care or treatment of patients or the promotion of public health.





TABLE OF CONTENTS

- General aspects
- **Conditions of in-house**
- Registering in-house device
- Conclusion

CONDITIONS OF MDR

Article 5(5)

- No transfer to another legal entity
- Appropriate QMS system
- Patient group specific needs not met by existing devices + justification
- Justification of manufacturing, modification and use
- Publicly available declaration
- Drawn up “technical documentation”
- Review of experience (~Post-Market Clinical Follow-up & Post-market surveillance)

National requirements

- Registration on FAMHP web portal
- Reporting serious incidents + corrective actions



CONDITIONS OF IVDR

Article 5(5)

- No transfer to another legal entity
- Appropriate QMS system
- Patient group specific needs not met by existing devices + justification (from 31.12.2030)
- Justification of manufacturing, modification and use
- Publicly available declaration
- Drawn up “technical documentation” (only for class D)
- Review of experience (~Post-Market Performance Follow-up & Post-Market Surveillance)
- Laboratory needs to fulfil to EN ISO 15189 or applicable national requirements, including concerning accreditation

Equal national requirements



➤ [FAMHP Q&A \(NL/FR\)](#)



ANOTHER LEGAL ENTITY

“The devices are not transferred to another legal entity”

Legal entity = one hospital?

Circulaire 655 => can be multiple hospital/hospital sites

TYPE OF HEALTH INSTITUTION	LEGAL BASIS
Locoregional clinical hospital network	Article 14/1, 1° of the coordinated law 10 July 2008
Hospital grouping	Article 8 of Royal Decree 30 January 1989
Hospital merger	Article 2 of Royal Decree 31 May 1989
Hospital association	Article 2, 1° of Royal Decree 25 April 1997



“TECHNICAL DOCUMENTATION”

1. Justification for in-house software

Written rationale explaining why the software meets Article 5(5) conditions:

- Absence of an equivalent CE-marked device on the market
- Software addresses specific needs of a specific target patient group
- Software will only be used within health institution, no transfer to another legal entity



“TECHNICAL DOCUMENTATION”

2. Description of device/software

Written rationale explaining why the software meets Article 5(5) conditions:

- Clear identification of the software
- Medical Intended Use
- Target Population and user profile
- Risk classification rationale per Annex VIII



“TECHNICAL DOCUMENTATION”

3. Demonstration compliance with Annex I (GSPR)

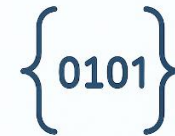
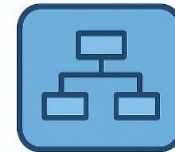
1. GSPR Checklist/matrix covering all applicable requirements
Includes references to evidence (e.g. test results, documentation, standards, reports,...)
2. Risk Management (ISO 14971 Principles)
Risk Analysis, risk evaluations, risk controls, residual risks assessments and benefit-risk justification
3. Clinical Evaluation
Justification of clinical safety and performance
Can be based on scientific literature or clinical experience
4. Evidence of appropriate software lifecycle processes
(IEC 62304 Principles)
5. User Documentation
User instructions
6. “PMS” & Documentation of corrective/preventive actions



“TECHNICAL DOCUMENTATION”

4. Manufacturing process and specifications

1. Software architecture
2. Code/algorithm
3. Design & development
4. Infrastructure
5. Interoperability
6. System Requirements
7. ...



“TECHNICAL DOCUMENTATION”

Best Practises

- ISO 14971 (Risk management)
- IEC 62304 (Medical Software Life Cycle Processes)
- IEC 82304-1 (Safety & Security of (standalone) health software)
- IEC 81001-5-1 & [MDCG 2019-16](#) (Cybersecurity medical device software)
- [MDCG 2020-1](#) (Guidance on clinical evaluation/performance evaluation)
- [MDCG 2023-1](#) (Guidance on in-house)
- ...



QUALITY MANAGEMENT SYSTEM

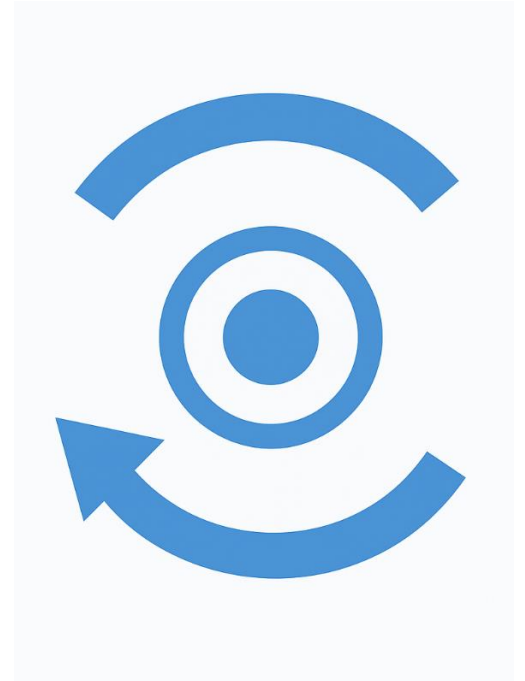
- The health institution must establish, document, implement, maintain, and keep up to date a QMS for the manufacture and use of in-house software.
- This can be implemented in the QMS of the health institution
- Document the processes necessary to ensure compliance with the requirements of Article 5(5) and Annex I of the MDR.



QUALITY MANAGEMENT SYSTEM

The QMS Shall include processes but is not limited to:

- Risk management
- Validations, verifications
- Version Control
- Responsibilities
- Control of externally provided processes, products and services
- “Post market” Surveillance/vigilance System
- Communication with Competent Authorities
- Processes for monitoring, analysis and continuous improvement



QUALITY MANAGEMENT SYSTEM

Best Practises

- ISO 13485:2016
- MDCG 2023-1
- ISO 14971
- IEC 62304, IEC 82304...



REGISTRATION

- In-house devices must be registered on the [FAMHP portal](#)
- This is mandatory for each “Device”
- More information can be found on [FAMHP website](#) (see webinar)



DECLARATION

- The Health institution draws up a declaration which it shall make publicly available the name and address of the manufacturing health institution:
 - the details necessary to identify the devices (identification within health institution, description, EMDN Code, Classification, Target patient group, intended use)
 - that the devices meet the general safety and performance requirements set out in Annex I to this Regulation (MDR/IVDR) and, where applicable, information on which requirements are not fully met with a reasoned justification therefor
- This declaration will be automatically generated after validation by the FAHMP
- (no additional separate declaration is required from the health institution)





TABLE OF CONTENTS

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WEBPORTAL FAMHP

The screenshot shows the top navigation bar of the FAMHP website. The language selector at the top left shows 'nl', 'fr', and 'en', with 'en' selected. On the top right, there is a link for 'Other information and services: www.belgium.be .be'. The main navigation menu includes 'About the FAMHP', 'Jobs', 'Publications', 'Press', 'Contact', 'Complaint', and 'Webportal', with 'Webportal' highlighted by a red box. Below the navigation bar is a search bar with the text 'Search' and a magnifying glass icon. The main header area features the 'famhp' logo and the tagline 'Your medicines and health products, our concern'. Below the header is a horizontal menu with five items: a home icon, 'Human use', 'Veterinary use', 'Information for the public', and 'Information for professionals'.



WEBPORTAL FAMHP

THE WEB PORTAL OF THE FAMHP

The web portal of the FAMHP has been developed in the framework of a project to reform the control policy of the FAMHP.

Objectives

- Rationalisation of the market surveillance by the competent services of the FAMHP.
- Optimising the planning and execution of inspections based on risk analysis.
- Reinforcing administrative simplification (observing the "only once"-principle, digitalisation of administrative processes).
- Ensuring transparency and synergies with all stakeholders.

At the moment, the web portal can be used by actors in the sector of medical devices and registered pharmacists-in-charge of pharmacies open to the public. They are responsible for the conformity of the information provided and for updating and completing their data when necessary. The FAMHP uses the information received via the web portal to optimise the efficiency of controls.

Medical devices

Access the module

Manufacturers and distributors of drugs and active substances (API)

Access the module

Pharmacies open to the public

Access to the inspection and e-mail address management module, the risk form and narcotics/psychotropics transactions

Access the Pharmacy Register module

Hospital pharmacies

Access the narcotics/psychotropics transactions module

Access the Pharmacy Register module



WEBPORTAL FAMHP

GENERIC PORTAL PRESENTATION

The portal is host to a number of applications allowing for the exchange of information and/or documents with the competent services of the FAMHP.



[+ More information](#)

Actors in the medical devices sector can register here. Registering on the portal allows you to :

- Register your activities (distributor, manufacturer, authorised representative,...)
- Apply for certificates of free sale in electronic format
- Notify the distribution of implants, of long-term invasive devices and of mobile applications
- Notify the manufacture of custom-made devices
- Notify devices manufactured and used only within health institutions
- Notify reprocessing of single-use devices and the use of reprocessed devices within health institutions
- Fill in an auto control form (risk analysis) and simplify the communication of inspection reports, corrective action plans and other useful documents between the actor and the inspection services
- Submit annually the declaration of turnover



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General questions:

✉ notifications_meddev@fagg-afmps.be

Technical problems:

✉ support_portal@afmps.be
☎ + 32 2 528 48 56

INFO AND DOCUMENTATION

- [You represent a Belgian company](#)
- [You represent a company located outside Belgium](#)
- [View the guides](#)
- [Search for registered companies](#)
- [Search devices](#)
- [List of medical devices](#)

You represent a Belgian company

If you are already registered with the FAMHP, please login using your identity card (Belgian eID). Your data will be recovered from the Crossroads Bank for Enterprises. If not, you must first register your business and configure your access details with the Management System Management Service ([user manual](#)).

[Configure my access](#)

[Login](#)

You represent a company located outside Belgium

If you are already registered with the FAMHP, please login using your username and password. If not, you must first register.

[Register](#)


[Login](#)

You are a member of the FAMHP

[Login](#)



WEBPORTAL | TILES = APPLICATIONS

NL FR EN Help Logout 

Federal Agency for Medicines and Health Products

My alerts

My activities

[Manage my activities](#)

My devices

[My distributed/manufactured devices](#)
[My notifications of manufacturing and reprocessing](#)


My company


Name of the company
Adress of the company

VAT number: BEXXXXXXXXXX
FAMHP number: BE/CA01/1-YYYYY

[Manage my company details](#)

My controls

Manufacturer
[Fill in my form](#) 
[My dossier](#)

Authorized representative
[Fill in my form](#) 
[My dossier](#)

My Free sale certificates

[Manage my certificate requests](#)

My Contributions

[Manage my Contributions](#)



WEBPORTAL | TILES = APPLICATIONS

NL FR EN Help Logout 

Federal Agency for Medicines and Health Products

My alerts

My company

Name of the company
Adress of the company

VAT number: BEXXXXXXXXXXX
FAMHP number: BE/CA01/1-YYYYY

[Manage my company details](#)

My activities


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[Fill in my form](#)
[My dossier](#)

My Free sale certificates

[Manage my certification requests](#)

My Contributions

[Manage my Contributions](#)

Not for in-house

Not for in-house



DIFFERENT STEPS IN REGISTRATION

1

Register the health institution as company and configure the access

2

Complete the information in "My enterprise"

3

Complete the activity in-house in "My activities"

**Necessary steps
for registration**

**Needs to be
completed once**

4

Notify the in-house medical devices in "My devices"

**One registration per
type of device !**

5


Complete the form "My controls"

**Not mandatory
but
recommended**



STEP 3 – REGISTERING IN-HOUSE ACTIVITY

1 Register the health institution as company and configure the access 

2 Complete the information in “My enterprise” 

3 Complete the activity in-house in “My activities”

Necessary steps
for registration

Needs to be
completed once

4 Notify the in-house medical devices in “My devices”


One registration per
type of device !


5 Complete the form “My controls”



*Not mandatory
but
recommended*



STEP 3 – REGISTER IN-HOUSE ACTIVITY

NL FR EN Help Your full name (CBE: 0436888493) Logout 

Federal Agency for Medicines and Health Products 

My company	My activities	My controls
<p>Name of your company</p> <p>Adress of the company</p> <p>VAT number: BEXXXXXXXXXX FAMHP number: BE/CA01/1- YYYY</p> <p>Manage my company details</p>	<p>Manage my activities</p>	<p>Manufacturer</p> <p>Fill in my form </p> <p>My dossier</p> <p>Distributor</p> <p>Fill in my form </p> <p>My dossier</p> <p>Download guideline(s)</p>



STEP 3 – REGISTER IN-HOUSE ACTIVITY



ER EN NL Contact Log out 

Activities

[Dashboard](#) [FAMHP activities](#)

Enterprise :

FAMHP number :	BE/CA01/1-YYYY
VAT number :	BEXXXXXXXXXX
Enterprise number (CBE) :	XXXXXXXXXX
Enterprise name :	Name
Language of communication :	French
Head office :	Full details

> EUDAMED data

In this section, you will find a table with the activities that your company has registered in EUDAMED.
We invite you to add any local units your company would have that are not mentioned in EUDAMED.
Please note that as long as the EUDAMED Device module is not fully functional, you can add in the table the risk classes of your devices for each activity.

> Registration for manufacturers, importers, authorised representative and SPPP

You can add your activities in the table you will find in this section.

> Registration for distributors, exporters, health institutions, manufacturers of custom-made devices and STHA

In this section you will find a table listing the activities described below.

Distributors and exporters must register their activity.
Health institutions can register their activities of reprocessing single-use devices and their activities of manufacturing devices in-house.
Manufacturers can register their activities of manufacturing custom-made devices.
Legal entities that offer installation or maintenance of medical devices at the patient's home can register as services and technical home assistants (STHA).



STEP 3 – REGISTER IN-HOUSE ACTIVITY

▼ Registration for distributors, exporters, health institutions, manufacturers of custom-made devices and STHA (service and technical home assistance)

In this section you will find a table listing the activities described below.

Distributors and exporters must register their activity.

Health institutions can register their activities of reprocessing single-use devices and their activities of manufacturing devices in-house.

Manufacturers can register their activities of manufacturing custom-made devices.

Legal entities that offer installation or maintenance of medical devices at the patient's home can register as services and technical home assistants (STHA).

You can use the following icons:

⊕ : to submit a new activity notification

🔍 : to consult/modify/stop your activities

Activity	Start date	
Custom-made manufacturer	Inactive	⊕
Distributor	Inactive	⊕
Exporter	Inactive	⊕
Service and technical home assistance **	Inactive	⊕
In-house	Inactive	⊕
Reprocessing	Inactive	⊕

**Article 59 - Law of 15 December 2013



STEP 3 – REGISTER IN-HOUSE ACTIVITY

In-house

[Modify](#)
[Stop](#)

Start date * 08/01/2020

Risk classification under the regulations² *

MDR					IVDR			
I	Is/Im/Ir	IIa	IIb	III	A	B	C	D
<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>	<input checked="" type="checkbox"/>

Supporting document according to Article 5 § 5 c) of Regulation 2017/746 (ISO 15 189 or other) [004-02-07-25.pdf](#)

Activity sites *

Site type	Address
Laboratory	def 123hhh 1000 100 Belgique

Responsible contact for the activity *

Role	Primary	Backup
Contact	Toto Test 0475123456 test@test.be	Pion Tartan tartanpion@mail.be
Vigilance	Toto Test 0475123456 test@test.be	User Sacex 0000 sacexuser@fhefhkjds.com

²Regulation (EU) 2017/745 concerning medical devices, Regulation (EU) 2017/746 concerning in vitro diagnostic medical devices
 * Required field



STEP 4 – REGISTERING IN-HOUSE DEVICE

1 Register the health institution as company and configure the access 

2 Complete the information in “My enterprise” 

3 Complete the activity in-house in “My activities” 

Necessary steps
for registration

Needs to be
completed once

4 Notify the in-house medical devices in “My devices”

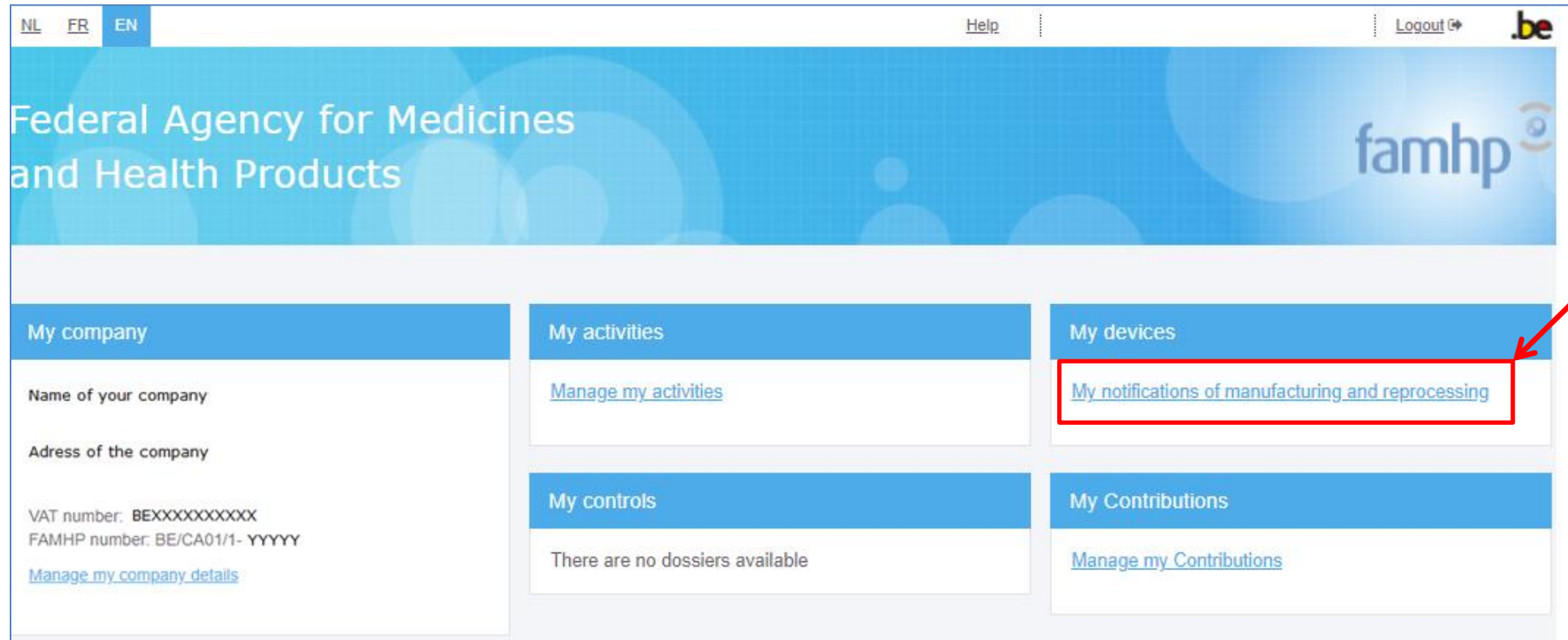
One registration per
type of device !

5 Complete the form “My controls”

*Not mandatory
but
recommended*



STEP 4 – REGISTER IN-HOUSE DEVICE



The screenshot displays the user interface of the Federal Agency for Medicines and Health Products (FAMHP). At the top, there are language selection options (NL, FR, EN), a 'Help' link, a 'Logout' button, and the '.be' domain logo. The main header features the text 'Federal Agency for Medicines and Health Products' and the 'famhp' logo. The interface is organized into several sections:

- My company:** Includes fields for 'Name of your company', 'Adress of the company', and 'VAT number: BEXXXXXXXXXX'. It also displays the 'FAMHP number: BE/CA01/1- YYYY' and a link to 'Manage my company details'.
- My activities:** Contains a link to 'Manage my activities'.
- My devices:** Contains a link to 'My notifications of manufacturing and reprocessing', which is highlighted with a red box and a red arrow pointing to it from the right.
- My controls:** Displays the message 'There are no dossiers available'.
- My Contributions:** Contains a link to 'Manage my Contributions'.



STEP 4 – REGISTER IN-HOUSE DEVICE

The screenshot displays the 'My devices' section of the FAMHP website. At the top, there are navigation links for 'NL', 'FR', and 'EN', along with 'Help' and 'Logout'. The main header includes the text 'My devices' and 'Notifications of manufacturing and reprocessing', with the 'famhp' logo on the right. Below the header, there are links for 'Manage my devices' and 'My manufacturers'. The 'My company:' section contains fields for 'Company FAMHP number', 'VAT number', 'Enterprise number (CBE)', 'Company', 'Language of communication', and 'Registered office'. The 'My drafts' section shows a table with columns for 'Economic operator', 'Device name', 'Notification type', 'Risk class', and 'Actions', with a message 'No results were found' and '0 result(s)'. The 'My devices' section features a status bar with 'Validated 2', 'Stopped 1', 'To be corrected 0', and 'To be validated 1'. Below this is a search filter with fields for 'FAMHP notification code', 'Economic operator', 'Device name', 'Notification type', and 'Risk class', and an 'Add' button highlighted with a red box and arrow. A table below the search filter shows one result with columns for 'FAMHP notification code', 'Economic operator', 'Device name', 'Notification type', 'Risk class', and 'Actions'. The bottom section, 'Managing in-house medical devices via File Interface', provides instructions on using a file interface to get a list of devices and includes buttons for 'Create file' and 'Upload modified file'.



STEP 4 – REGISTER IN-HOUSE DEVICE

Identification of the devices

Identification (model, serial number...): *
Press enter to confirm Add

Description and intended use: *

Class: *
If you cannot see your risk class, please check if it exists in "My activities"

Class justification (following the classification rules of annex VIII of the regulation (EU)2017/746): *

EMDN code: ⓘ *



STEP 4 – IMPORTANT TERMS

One registration per type of device

- Same risk class
- Identical description and intended use
- Identical EMDN code

Identification (model, serial number,...): needs to be unique, unambiguous identification inside the health institution and the accompanying documentation.

Description and intended use:

- Nature of device (e.g. reagents, software, etc.)
- Intended use (e.g. aide in detection of cancer, etc.)
- Target patient group (children, elderly women with breast cancer, etc.)



STEP 4 – IMPORTANT TERMS

Risk class

- Used classification rules according Annex VIII (e.g. rule 11 MDR)
- Multiple rules applicable? Risk according to rule with highest risk

Justification of risk class

- Number of classification rule + subrule
- Short justification why rule (and subrule) applies

EMDN code

- [European medical device nomenclature](#)
- Free, online available site of [EC](#) (English) and [Eudamed](#) (English + translations)
- Training available on EMDN (history, structure, how to select, etc.) on [EC website](#)
- Select most appropriate EMDN code



STEP 4 – REGISTER IN-HOUSE DEVICE

Declarations

You must agree to all of the statements below followed by an asterisk.

The documentation referred to in Article 5 §5.g of Regulation (EU) 2017/746 is kept at the disposal of the FAMHP. *

I declare that I meet the requirements of Article 5 §5 of Regulation (EU) 2017/746. *

Do the devices in this notification meet the general safety and performance requirements set out in Annex I of Regulation (EU) 2017/746? *

Yes, for all requirements

Yes, except for the following requirements:

Please provide in the field below information and a reasoned justification for the requirements not being met.


Once your notification is validated by the FAMHP, the public statement referred to in Article 5, §5, f) of Regulation (EU) 2017/746 will be published on the FAMHP website. To this end, the following information will be made public:


- The name and address of the health institution;
- The identification of the devices;
- An indication of whether these devices fully or partially meet the general safety and performance requirements set out in Annex I of Regulation (EU) 2017/746 and, where applicable, information and reasoned justification on the requirements not being met.

[Cancel](#) [Save temporarily](#) [Submit](#)




STEP 4 - AFTER VERIFICATION BY FAMHP

NL FR EN Help 

Federal Agency for Medicines and Health Products 

GENERIC PORTAL PRESENTATION

The portal is host to a number of applications allowing for the exchange of information and/or documents with the competent services of the FAMHP.



[+ More information](#)

INFO AND DOCUMENTATION

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- [You represent a company located outside Belgium](#)
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You are a member of the FAMHP

[Login](#)


Federal Agency for Medicines and Health Products
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1210 Bruxelles
General questions:
✉ notifications.meddev@fagg.afmps.be
Technical problems:
✉ support_portal@afmps.be



AFTER VERIFICATION BY FAMHP

Distributeur
 Importateur
 Représentant autorisé
 Etablissement de santé

Type de dispositif: Notification de dispositifs de diagno... Classe de risque: ...

Réf: ...
Cla: ...

Notification de dispositifs de diagnostic in vitro in-house

Numéro entreprise AFMPS: 71072
Numéro de l'entreprise (BCE): 0437882546
Etablissement de santé: CENTRUM VOOR MEDISCHE ANALYSE
Modèle du dispositif ou nom commercial: 0349
Description et utilisation prévue: kit voor kwantitatieve bepaling van kwik in bloed bij de algemene bevolking als weergave van de (beroeps)blootstelling aan dit zware metaal. De kit bestaat uit: Kalibrator 07949, Controle 07950-07951, Reagens 07968, Reagens 76058, Reagens 07947
Classe de risque: Classe IVDR B
Code EMDN: W 01 01 02 99
Code notification AFMPS: BE/CA01/1-71072-02867-IHIVD

Les dispositifs satisfont aux exigences générales en matière de sécurité et de performances énoncées à l'annexe I du règlement (UE) 2017/746
Sauf pour les exigences suivantes:
Evaluatie van de metrologische traceerbaarheid wordt niet voldaan. Rechtvaardiging: - afwezigheid van commerciële standaarden en controlemateriaal die via geschikte referentiemeetprocedures en/of geschikte referentiematerialen van een hogere metrologische orde werden getoetst

[Fermer](#)

Rechercher

Notifications

Distribution 0

Code notification

BE/CA01/1-71072							
BE/CA01/1-71072							
BE/CA01/1-71072							
BE/CA01/1-71072-02867-IHIVD	CENTRUM VOOR MEDISCHE...	0413	In-house IVDR	Classe IVDR B	PUBLISHED		
BE/CA01/1-71072-02877-IHIVD	CENTRUM VOOR MEDISCHE...	0559	In-house IVDR	Classe IVDR C	PUBLISHED		
BE/CA01/1-71072-02836-IHIVD	CENTRUM VOOR MEDISCHE...	0400	In-house IVDR	Classe IVDR B	PUBLISHED		

Actions



STEP 4 – REGISTERING IN-HOUSE DEVICE


1 Register the health institution as company and configure the access 

2 Complete the information in “My enterprise” 

3 Complete the activity in-house in “My activities” 

Necessary steps
for registration

Needs to be
completed once

4 Notify the in-house medical devices in “My devices” 

One registration per
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*Not mandatory
but
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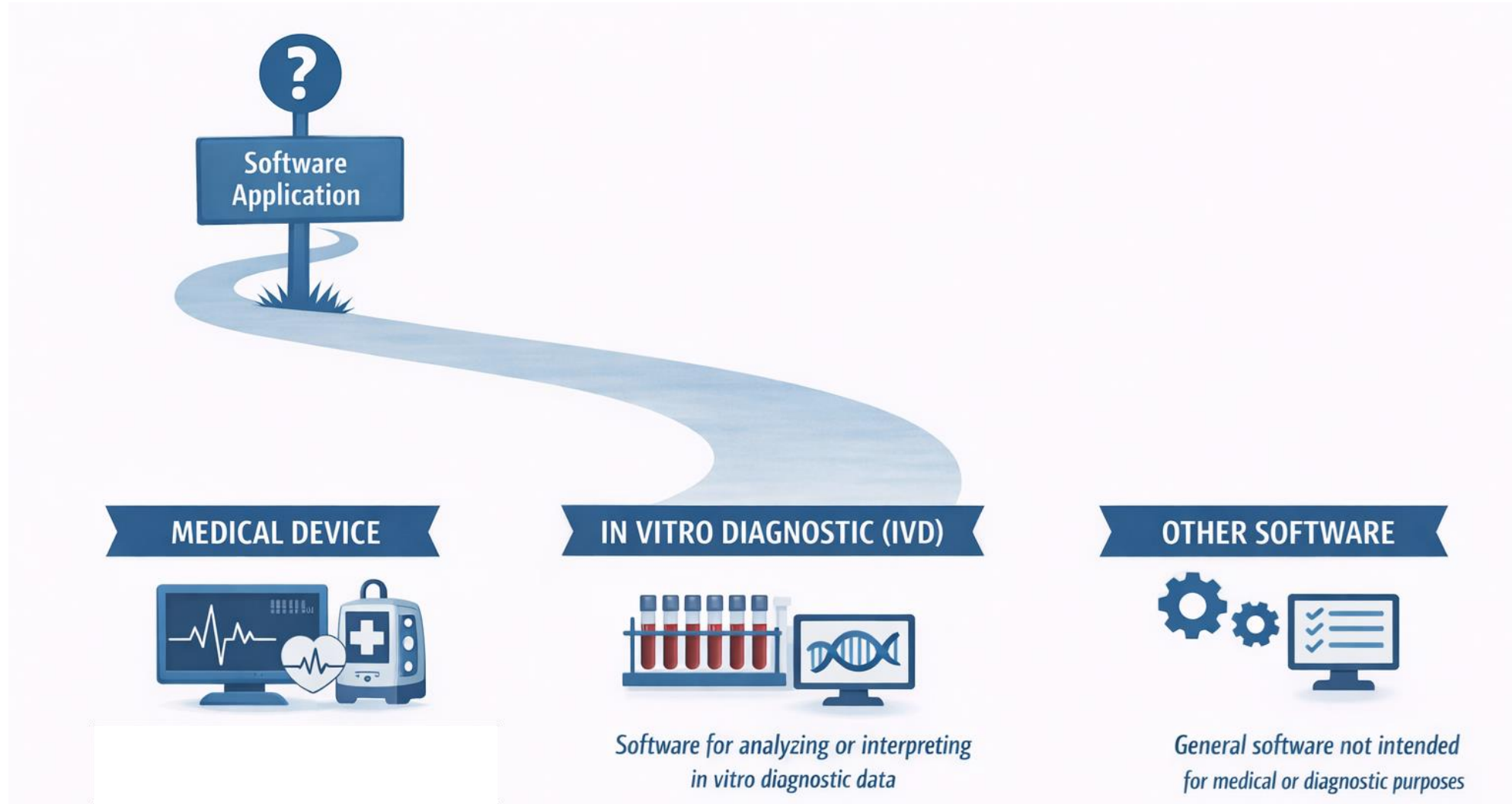




TABLE OF CONTENTS

- General aspects
- Conditions of in-house
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- **Conclusion**

STARTING POINT - QUALIFICATION



SUMMARY CE-MARKED VS IN-HOUSE

ASPECT	CE-MARKED DEVICE	IN-HOUSE DEVICE
Market access	Placed on market, broad distribution	Internal use only, no market access
MDR/IVDR compliance	Full MDR/IVDR requirements	Article 5(5) conditions, Annex I
Technical documentation	Mandatory	Not mandatory A lot of similar documents
Conformity assessment	Nearly always notified body	Self-assessment
Scalable	Yes	No, except within same network



QUESTIONS?



CONTACT

Federal Agency for Medicines and Health Products - FAMHP

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tel. + 32 2 528 40 00

welcome@fagg-afmps.be
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Info.meddev@fagg-afmps.be

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