Digital Health Regulatory Navigator (EU)

Nine steps to assess if your **standalone software** is subject to **medical device regulations** of the European Union and to develop a **regulatory strategy**.

Idea Name	Date	Iteration

1. INTENDED PURPOSE

Through the **intended purpose**, the manufacturer defines the purpose of a software product, determining whether it is subject to medical device regulations. Sales and marketing material should reflect the **intended purpose**. Complete the steps below, and then create a summary highlighting the key elements of the **intended purpose**. Refer to the **navigator guideline** for definitions and further details.

1.1 Main Purpose and Claims
- Describe the main purpose of your solution
- Mention whether or not it serves a **medical purpose** (providing information, alone or in combination to: treat, diagnose, predict, prevent, monitor, or alleviate a disease, injury, or disability; investigate an anatomy, a physiological or pathological process or state; or providing information by means of in vitro examination)
- Mention specific **claims** and **disclaimers** concerning the performance, the clinical benefits and non-clinical benefits of the device

1.2 Intended Medical Indication
If applicable:
- List specific conditions or diseases targeted by your solution
- Utilize ICD codes for condition identification (WHO classification)

1.3 Contraindications
If applicable:
- Identify conditions preventing safe and effective use
- Outline non-use circumstances (situation, patient-specific)

1.4 Patient Population
- Describe directly or indirectly affected patient populations
- Focus on demographic characteristics: age, gender, specific health conditions, weight, prevalent diseases, physical limitations
- Indicate healthcare professionals in user profile if software operated by them

1.5 User Profile and Qualification
- Identify software users (e.g., patients, doctors, nurses)
- List skills required for usage: qualifications, training, technical proficiency, education, language, language complexity, typical tasks
- Mention your targeted market (country, region)

1.6 Part of Body
- Detail device patient contact: physical (energy, material) or immaterial (signals, information), body parts, tissue, or if no direct body contact is involved

1.7 Context of Use and Environment
- Outline additional software or hardware requirements
- Address use aspects: frequency, duration of use, results, location, environmental conditions
- Differentiate mobile and stationary use and clinical environment considerations

1.8 Connected Devices and Accessories
- List connected devices and accessories used with the device such as wearables (smartwatches, sensors)

1.9 Operating Principle
- Outline the high-level operating principle, explaining the core functionality
- Describe inputs and outputs (e.g., image as input and diagnosis as output)
- Include typical software workflows

1.10 Intended Purpose Summary
- Putting it all together: Provide a summary of the intended purpose in no more than three sentences, including the medical purpose, claims, patient population, user profiles, context and environment of use, and the operating principle

2. MEDICAL DEVICE REGULATIONS QUALIFICATION

Review the questions below, check relevant boxes, and determine, based on the **intended purpose**, if your software is classified as a medical device and subject to **medical device regulations**.

Start

2.1 Is the product a set of instructions that process **input data** (any data provided to software) and creates **output data** (any data produced by software)?
Reasoning:

☐ no → **Not covered by this navigator,** the product is not software

☐ yes ↓

2.2 Is the software at least one of the following: **'accessory for a medical device'** or **'software driving or influencing the use of a (hardware) medical device'**?
Reasoning:

☐ yes → Covered by medical device regulations, but **not by this navigator** as the regulatory requirements also depend on the related hardware device; this navigator focuses on **standalone software**

☐ no ↓

2.3 Is the software performing an action on data different from **storage, archival, communication or simple search**?
Reasoning:

☐ no → Not covered by medical device regulations, continue with section 8

☐ yes ↓

2.4 Is the action for the benefit of **individual** patients?
Reasoning:

☐ no → Not covered by medical device regulations, continue with section 8

☐ yes ↓

2.5 Is the software a **medical device** according to the European Union definition of a medical device (i.e., does it serve a medical purpose, see section 1.1)?
Reasoning:

☐ no → Not covered by medical device regulations, continue with section 8

☐ yes → Covered by medical device regulations, continue with section 3

3. TYPE OF MEDICAL DEVICE REGULATION

Review the questions below to see if your software product meets the criteria for the **Medical Device Regulation (MDR)** or **In Vitro Diagnostic Medical Device Regulation (IVDR)** based on its **intended purpose**.

Continue from section 2, covered by medical device regulations

3.1 Does the software provide information within the scope of the **in vitro diagnostic (IVD) medical device** definition provided by the European Union?
Reasoning:

☐ no → Covered by MDR, continue with section 4.1

☐ yes ↓

3.2 Does the software provide information based on data obtained by IVD medical devices **only**?
Reasoning:

☐ yes → Covered by IVDR, continue with section 4.2

☐ no ↓

3.3 Is the intended purpose **substantially driven** by IVD data sources (IVD data needs to be decisive for overall result)?
Reasoning:

☐ no → Covered by MDR, continue with section 4.1

☐ yes → Covered by IVDR, continue with section 4.2

4. RISK CLASSIFICATION

Identify your software's risk class according to **medical device regulations**, ranging from class I or A (lowest) to class III or D (highest). Focus on field **4.1** for **MDR** or field **4.2** for **IVDR**, read through all rules and based on your **intended purpose** select the **highest applicable risk class**.

4.1 Medical Device Regulation (MDR) Risk Class
- Examine all 22 MDR rules (see **navigator guideline** appendix). Below you find rules most important to software, most importantly Rule 11

Rule 11a (Rule 11 paragraphs 1-3)	☐ Applicable ☐ Not applicable	Identified risk class and reasoning:
Rule 11b (Rule 11 paragraph 4)	☐ Applicable ☐ Not applicable	Identified risk class and reasoning:
Rule 11c (Rule 11 paragraph 5)	☐ Applicable ☐ Not applicable	Identified risk class and reasoning:
Rule 15	☐ Applicable ☐ Not applicable	Identified risk class and reasoning:
Rule 22	☐ Applicable ☐ Not applicable	Identified risk class and reasoning:
Rule ___	☐ Applicable ☐ Not applicable	Identified risk class and reasoning for other rules besides those mentioned above:
Rule ___	☐ Applicable ☐ Not applicable	Identified risk class and reasoning for other rules besides those mentioned above:
MDR Highest Risk Class: Applicable MDR Rule:		Highest risk class and applicable rule:

4.2 In Vitro Diagnostic Medical Device Regulation (IVDR) Risk Class
- Examine all 7 IVDR rules (see **navigator guideline** appendix)

Rule 1	☐ Applicable ☐ Not applicable	Identified risk class and reasoning:
Rule 2	☐ Applicable ☐ Not applicable	Identified risk class and reasoning:
Rule 3	☐ Applicable ☐ Not applicable	Identified risk class and reasoning:
Rule 4	☐ Applicable ☐ Not applicable	Identified risk class and reasoning:
Rule 5	☐ Applicable ☐ Not applicable	Identified risk class and reasoning:
Rule 6	☐ Applicable ☐ Not applicable	Identified risk class and reasoning:
Rule 7	☐ Applicable ☐ Not applicable	Identified risk class and reasoning:
IVDR Highest Risk Class: Applicable IVDR Rule:		Highest risk class and applicable rule:

5. EVALUATION

Plan the evaluation to generate **clinical evidence** based on the three key components below, tick applicable boxes and fill the blanks with corresponding content.

☐ **Clinical Evaluation (MDR)** OR ☐ **Performance Evaluation (IVDR)**

5.1 Valid Clinical Association/Scientific Validity
- Is the output of the software clearly associated with a clinical condition or a physiological state? Do you have scientific data for acceptance of the underlying principle of the algorithm?

☐ Sufficient existing evidence from publications (e.g., from PubMed), state of the art, professional guidelines:

☐ Not sufficient existing evidence → evidence through own data from clinical research or a **premarket clinical study**

5.2 Technical/Analytical Performance
- Can the software accurately, reliably and precisely generate the intended output, from the input data?

State planned software verification and validation activities to collect evidence:

5.3 Clinical Performance
- Does the software achieve its intended purpose in the target population and lead to a clinical benefit?

Claimed clinical benefits in **intended purpose**:

☐ Sufficient existing evidence from equivalent devices (e.g., from PubMed) supporting clinical benefit claims:

☐ Not sufficient existing evidence for clinical benefit claims → evidence through own data from a **premarket clinical study**
☐ Clinical benefit claims **not** specified by a **measurable, patient-specific clinical outcome**
→ clinical relevant outputs achieved through demonstrated predictable and reliable use and usability

→ Premarket Clinical Study
☐ **Clinical Investigation (MDR)** OR ☐ **Performance Study (IVDR)** together with
☐ Probably no premarket clinical study required

Study execution partner institution (e.g., university hospital):

6. REGULATORY ROADMAP

Develop a roadmap using timestamps and horizontal bars with labels to indicate tasks like **software development**, **risk management**, **cybersecurity management**, **usability evaluation**, and **clinical/performance evaluation**.

Milestones

Idea | Start building Quality Management System (QMS) | Prototype finished | ☐ Initial Contact with Notified Body | Product Development & User Manuel Complete | Final Usability and Clinical/ Performance Evaluation | Final Technical Documentation and QMS | CE marking (MDR/IVDR) ☐ with/ ☐ without Notified Body & EUDAMED Registration | **Market Access** | Post-market Activities

Optional: Identify additional applicable regulations and add them to the roadmap (e.g., GDPR, AI Act)

7. STAKEHOLDERS AND COSTS

Map **regulatory stakeholders** and **costs** based on your previous findings.

7.1 Regulatory Stakeholder Map
- Identify the roles within your team that are internal stakeholders, and also consider any additional external stakeholders that should be involved

External Stakeholder

Internal Stakeholder

7.2 Regulatory Costs Estimation Table
- List cost factors and note their frequency of occurance and magnitude (low, middle, high)

Cost Factors	Frequency	Magnitude

8. SYNTHESIS

Summarize the key insights from your regulatory strategy with the help of the template below. Then identify your main challenges.

8.1 Regulatory Strategy Summary Statement

We will design General description (e.g., mobile app):

intended to Medical or non-medical purpose and claims made (e.g., clinical benefit claims):

through Operating principle: .

It will be used by Target or user group: .

The solution will be Medical device, In vitro diagnostic medical device or non-medical device:

with Identified risk class or if non-medical device no applicable risk class:

and evidence collection Through own premarket study, existing data (medical devices) or no evidence required (non-medical devices): .

8.2 Key Challenges with Current Regulatory Strategy

State challenges and problems that you can identify for your current regulatory and the broader business strategy based on the previous findings:

9. PIVOTING

In light of these findings, are you adjusting your **intended purpose** along with both your regulatory and broader business strategy? Examine possible reasons, make a decision and define next steps.

9.1 Reasons for Changing or Maintaining Regulatory Strategy
☐ Medical device as a competitive advantage (proofs safety, performance, benefits) over the following competitors:

☐ Medical device is beneficial for the following country-specific reimbursement pathways with health insurers or the government:

☐ Business case and intended revenue streams do not require a medical device
☐ Market potential for a specific target group can only be unlocked as a medical device
☐ First, introduce unregulated lifestyle or research only solution to gather data, then switch to medical device later
☐ Becoming a medical device is time-consuming, resource-intensive, and expensive
☐ Markets in other non-EU countries are more attractive (might be less regulated)
☐ Current claims regarding clinical benefits require expensive premarket clinical studies
☐ Risk Class I or Class A do not require a notified body, which is faster and cheaper
☐ Enhances credibility as a medical device, thereby increased adoption among (professional) users
☐ Other reasons:

Think about further reasons, such as strong competition, consumer demands or current access to funding that could further influence your regulatory strategy:

9.2 Decision on Changing or Maintaining Regulatory Strategy
☐ Maintain current strategy
☐ Change strategy to fall under medical device regulations
☐ Change strategy to avoid falling under regulations
☐ Change strategy to:

9.3 Points of Action

State the next steps for the intended purpose and the regulatory and broader business strategy that build on the decision above and address the key challenges:

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