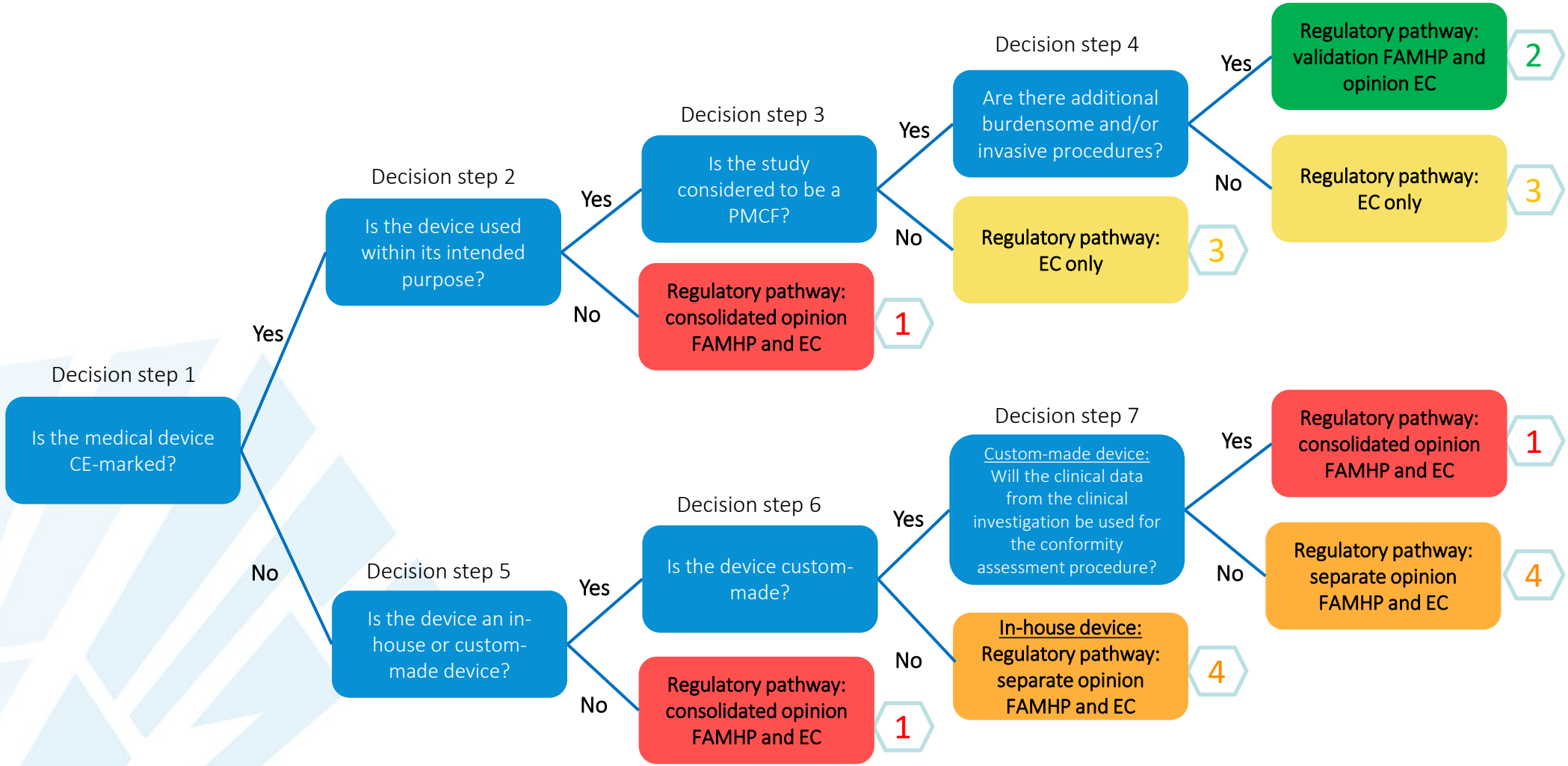
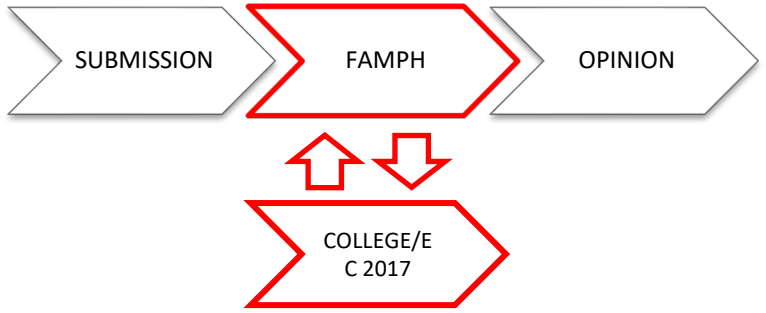
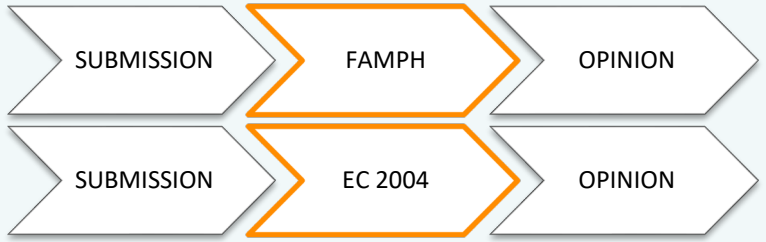
Regulatory path decision tree for medical device studies*

* See page 3



Source: FAMHP guideline submission processes of clinical investigatons according to MDR in Belgium (version 9.0 – 24.02.2023, figure 3: Decision tree)

4 Workflows

Flow 1: Consolidated opinion FAMHP and EC 2017 1		→ Clinical investigation **with CE-marked device** that is used **outside its intended purpose** → Clinical investigation **with device without CE marking** that is not a custom-made or in-house device → Clinical investigations involving **custom made devices** for which data **will be used for conformity assessment**
Flow 2: FAMHP validation and EC 2017 opinion 2		→ Post-Market Clinical Follow-up investigation (**PMCF**) **involving additional burdensome or invasive procedures**
Flow 3: EC 2004 only 3		→ **PMCF without additional burdensome or invasive procedures** (Law on experiments) → **Other** clinical investigation **with CE-marked device** that is **used for its intended purpose** (RD on clinical investigations)
Flow 4: Separate opinion FAMHP and EC 2004 4		→ Clinical investigations involving **in-house medical devices** → Clinical investigations involving **custom made devices** for which data will **not be used for conformity assessment**

Definition & compliance

*What is a medical device?

The definition as defined in the MDR is as follows:

"Any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- *diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,*
- *diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,*
- *investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,*
- *providing information by means of in vitro examination of specimens derived from the human body, including organ, blood and tissue donations, and which does not achieve its principal intended action by pharmacological, immunological or metabolic means, in or on the human body, but which may be assisted in its function by such means.*

The following products shall also be deemed to be medical devices:

- *devices for the control or support of conception;*
- *products specifically intended for the cleaning, disinfection or sterilisation of devices as referred to in MDR Article 1(4)*
- *products listed in Annex XVI of the MDR."*

It is important to note that software, including Artificial Intelligence and Machine Learning technologies, may qualify as a medical device if these technologies do have a specific medical purpose. The fact that the tool does not impact the treatment of the patient does not change this.

Is the Medical Device Regulation (MDR) applicable to my study?

If the safety and/or performance of a medical device is assessed using data originated from study participants, the study is a clinical investigation according to the definition of the MDR.

Once a prototype is available, even though this prototype may not fulfil its intended medical purpose yet, the product already qualifies as a medical device. A study to assess safety and/or performance of this prototype must be classified as a clinical investigation. If the study generates data to develop a first prototype, the study should not be qualified as a clinical investigation and the MDR is not applicable.

It is important to clearly define the purposes and the objectives of the study and the device in the protocol to avoid misunderstandings in the study qualification.