Briefing Book

January 2020

Medical devices

In vitro diagnostic medical devices

**Contents**

[I. General information 3](#_Toc32745886)

[I-1. Medical indications 3](#_Toc32745887)

[I-2. Product development rationale 3](#_Toc32745888)

[(Justification of product creation) 3](#_Toc32745889)

[I-3. Target patients 3](#_Toc32745890)

[I-4. Additional information 4](#_Toc32745891)

[II. Regulatory information 5](#_Toc32745892)

[III. Product information 6](#_Toc32745893)

[III-1. Product composition 6](#_Toc32745894)

[III-2. Product Cleaning / Disinfection / Sterilisation 7](#_Toc32745895)

[IV. Non-clinical evaluation 7](#_Toc32745896)

[IV-1. Non-clinical recommendations 7](#_Toc32745897)

[IV-2. Non-clinical information 7](#_Toc32745898)

[V. Clinical evaluation 8](#_Toc32745899)

[V-1. Clinical information 8](#_Toc32745900)

[V-2. Study “XXX” (In the event of several studies, complete another section V-2) 8](#_Toc32745901)

[V-3. Additional information 8](#_Toc32745902)

[VI. Device performance (particularly for IVDMDs and MDs with a measuring function) 9](#_Toc32745903)

[VII. CE marking and marketing of the device 9](#_Toc32745904)

[VII-1. Progress status with a view to CE marking 9](#_Toc32745905)

[VII-2. CE marking (position with respect to art 54 procedure) 9](#_Toc32745906)

[VII-3. Market presence 10](#_Toc32745907)

[VIII. QUESTIONS (6 maximum) and supported draft RESPONSES 10](#_Toc32745908)

1. General information

I-1. Medical indications

|  |  |  |
| --- | --- | --- |
| a | Product description |  |
| b | Intended purpose / medical indication |  |
| c | Associated medical procedures |  |
| d | Place in the therapeutic strategy |  |

I-2. Product development rationale

(Justification of product creation)

I-3. Target patients

|  |  |  |
| --- | --- | --- |
| a | Gender | male  female |
| b | Age |  |
| d | Expected number in France |  |
| e | Users concerned | Healthcare professionals  Patients (condoms, self-test, etc.) |
| f | If healthcare professionals concerned, which? |  |

I-4. Additional information

|  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- |
| a | Impact on clinical practices  *(from the point of view of the practitioner for an MD and/or the biologist for an IVDMD)* | Nil or low  Moderate  Strong | | | | |
|  |  | Justification: | | | | |
| b | Degree of novelty | Substantial novelty with incremental technology and moderate clinical impact  Innovation with technological breakthrough or strong clinical impact  Major innovation with technological breakthrough and strong clinical impact  Other (specify): | | | | |
|  |  | Justification with Package leaflet to be transmitted | | | | |
| c | Iteration of an existing device | yes  no | | | | |
| If yes, which? | |  | | |
| If yes, modification |  | | of purpose / indication | |
|  | | of quality system *(Modification of manufacturing process, etc.)* | |
|  | | of design | |
|  | | of performance *(Reduction of detection threshold, etc.)* | |
|  | | of user population | |
|  | | other, specify |  |

1. Regulatory information

|  |  |  |
| --- | --- | --- |
| a | Specify the applicable Directives/regulation:  *(see FAQ)* | 90/385/EEC relating to active implantable medical devices  93/42/EEC concerning medical devices  98/79/EC on in vitro diagnostic medical devices  Regulation (EU) 2017/745 on medical devices  Regulation (EU) 2017/746 on in vitro diagnostic medical devices  Regulation (EU) 207/2012 on electronic instructions for use of medical devices  Regulation (EU) 722/2012/EC concerning particular requirements with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin  Other, specify |
| b | Specify the CND classification (optional): |  |
| c | Presence of a person responsible for regulations within the company | yes  no |
| d | Presence of a person responsible for quality assurance within the company | yes  no |
| e | Detail the conformity assessment procedures (specify the annexes implemented) |  |

1. Product information

III-1. Product composition

|  |  |  |  |
| --- | --- | --- | --- |
| a | Device composition |  | |
| B | Device containing a **medicinal product**  (Directive 2001/83/EC) | | yes  no |
| Nature | |  |
| Competent regulatory body | |  |
| Description of usefulness of addition of the substance | |  |
| Progress status of the procedures concerning the medicinal product and list of the competent authorities consulted in the procedures | | Free text field |
| C | Device containing a **blood component**  (Directives 2000/70/EC and 2001/104/EC) | | yes  no |
| Nature | |  |
| Competent regulatory body | |  |
| Description of usefulness of addition of the substance | |  |
| Progress status of the procedures concerning the blood component and list of the competent authorities included in the procedures | | Free text field |
| D | Device containing a **product of animal origin** | | yes  no |
| Nature | | *(e.g.: collagen)* |
| Source / Origin | | *(e.g.: porcine, bovine)* |
| Description of usefulness of addition of the substance | |  |
| Progress status of the procedures concerning the product of animal origin and list of the competent authorities included in the procedures | | Free text field |
| E | Device containing **nano-elements** | | yes  no |
| Nature | |  |
| Description of usefulness of use of nano-elements | |  |
| F | Device containing an artificial **radionuclide** | | yes  no |
| G | Device emitting **ionising radiation** | | yes  no |
| H | Device containing **latex** | | yes  no |
| I | Device containing **phthalates** | | yes  no |
| J | Devices containing CMR substances and toxic to reproduction (Regulation (EU) 2017/745 An I chap II E 10.4.1) | | yes  no  Specify the substances and justify their addition |
| K | Presence of software  Use  Production  Storage of patient data  Existence of connectivity feature | | yes  no  Free text field  Free text field  yes  no  yes  no |
| L | Additional information | |  |

III-2. Product Cleaning / Disinfection / Sterilisation

|  |  |  |  |
| --- | --- | --- | --- |
| a | Is the product: | Sterile   To be sterilised  To be disinfected | |
| d | Specify the type of sterilisation: | | Select an item |
| e | Claim relative to conformity with sterilisation, disinfection and/or cleaning standards | | Free text field to be supported |

1. Non-clinical evaluation

IV-1. Non-clinical recommendations

|  |  |
| --- | --- |
| Non-clinical evaluation status | Select an item |
| EN ISO 10993 series  Chemical characterisation performed  Biological risk assessment  Other | Specify  Specify On the MD  Equivalence claim |
| List of harmonised standards claimed | Specify |
| List of non-harmonised standards claimed | Specify |
| Technical specification lists followed | Specify |

IV-2. Non-clinical information

|  |
| --- |
| The conformity claim is based on non-clinical data specifically concerning Select an item: |
| In the event of an equivalent product, specify which and justify the equivalence |

1. Clinical evaluation

|  |  |  |
| --- | --- | --- |
|  | **Clinical development strategy**  Clinical investigations on the MD/performance studies on the IVDMD  Equivalence  Bibliography |  |

V-1. Clinical information

|  |  |  |
| --- | --- | --- |
| a | Number of clinical investigations/performance studies  (completed or ongoing) |  |
| b | Total number of patients included in these trials and in France |  |
| c | If clinical trials are planned, provide a brief description of their aim |  |

V-2. Study “XXX” (In the event of several studies, complete another section V-2)

|  |  |  |
| --- | --- | --- |
| a | Study title (and Eudract No.) |  |
| b | Study year |  |
| c | Country where the study was conducted |  |
| d | Study aim |  |
| e | Devices used |  |
| f | Study type |  |
| g | Study subjects *(number, inclusion criteria)* |  |
| h | Follow-up *(duration, observation frequency)* |  |
| i | Assessment criteria |  |
| p | Results |  |

V-3. Additional information

|  |  |  |
| --- | --- | --- |
| **a** | Description of planned auxiliary medicinal products  The planned concomitant therapies (authorised and prohibited) comply with the recommendations detailed in the documents provided in support of the clinical trial authorisation application (IB/SmPC):  (Any divergence must be justified) |  |
| b | Risk management strategy |  |

1. Device performance  
   (particularly for IVDMDs and MDs with a measuring function)

|  |  |  |
| --- | --- | --- |
| a | Analytical sensitivity |  |
| b | Diagnostic sensitivity |  |
| c | Analytical specificity |  |
| d | Diagnostic specificity |  |
| e | Accuracy |  |
| f | Repeatability |  |
| g | Reproducibility |  |
| h | Interference |  |
| i | Limits of detection |  |
| j | Other performance(s), specify: |  |

1. CE marking and marketing of the device

VII-1. Progress status with a view to CE marking

|  |
| --- |
| Marking procedure Select an item |
| Specify whether the MD falls within the scope of the special procedure defined in article 54 of regulation (EU) 745/2017. |

VII-2. CE marking (position with respect to art 54 procedure)

|  |  |  |
| --- | --- | --- |
| a | Year of first application of CE mark |  |
| b | Identification number and name of the notified body consulted for the first CE mark |  |
| c | Year of application of the current CE mark |  |
| d | Identification number and name of the notified body consulted for the current CE mark *(if different from above)* | If applicable |
| e | Other information:  Information about the company conducting the product (age, size, presence on the medical device market, organisation chart) | Free text field |
|  | QMS maturity (certification obtained?), | If applicable   * Certification obtained * Composition of subcontracted steps * Consultant used |

VII-3. Market presence

|  |  |  |
| --- | --- | --- |
| a | Current or envisaged place of marketing  Europe  USA  Canada  China  Japan  Australia-New Zealand  Other, specify | Specify the records, approvals obtained or project status |

1. QUESTIONS (6 maximum) and supported draft RESPONSES

|  |
| --- |
| Question |
|  |
| Draft response |
|  |

|  |  |  |
| --- | --- | --- |
| **I hereby certify that the information provided in this document is accurate** | | |
| **Signed on:** | **Signatory’s surname and first name** |  |
| **Signature** | |