Agence nationale de sécurité du médicament et des produits de santé

# BRIEFING BOOK

## MEDICAL DEVICES
## IN VITRO DIAGNOSTIC MEDICAL DEVICES

**JANUARY 2020**

# Contents

# I. 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

<table>
<tr><td>a</td><td>Impact on clinical practices<br>(from the point of view of the practitioner for an MD and/or the biologist for an IVDMD)</td><td colspan="4">☐ Nil or low ☐ Moderate ☐ Strong</td></tr>
<tr><td></td><td></td><td colspan="4">Justification:</td></tr>
<tr><td>b</td><td>Degree of novelty</td><td colspan="4">☐ Substantial novelty with incremental technology and moderate clinical impact<br>☐ Innovation with technological breakthrough or strong clinical impact<br>☐ Major innovation with technological breakthrough and strong clinical impact<br>☐ Other (specify):</td></tr>
<tr><td></td><td></td><td colspan="4">Justification with Package leaflet to be transmitted</td></tr>
<tr><td rowspan="9">c</td><td rowspan="9">Iteration of an existing device</td><td colspan="4">☐ yes ☐ no</td></tr>
<tr><td colspan="2">If yes, which?</td><td colspan="2"></td></tr>
<tr><td rowspan="7">If yes, modification</td><td>☐</td><td colspan="2">of purpose / indication</td></tr>
<tr><td>☐</td><td colspan="2">of quality system (Modification of manufacturing process, etc.)</td></tr>
<tr><td>☐</td><td colspan="2">of design</td></tr>
<tr><td>☐</td><td colspan="2">of performance (Reduction of detection threshold, etc.)</td></tr>
<tr><td>☐</td><td colspan="2">of user population</td></tr>
<tr><td>☐</td><td>other, specify</td><td></td></tr>
</table>

# II. REGULATORY INFORMATION

| | | |
|---|---|---|
| a | Specify the applicable Directives/regulation: *(see FAQ)* | ☐ 90/385/EEC relating to active implantable medical devices<br>☐ 93/42/EEC concerning medical devices<br>☐ 98/79/EC on in vitro diagnostic medical devices<br>☐ Regulation (EU) 2017/745 on medical devices<br>☐ Regulation (EU) 2017/746 on in vitro diagnostic medical devices<br>☐ Regulation (EU) 207/2012 on electronic instructions for use of medical devices<br>☐ Regulation (EU) 722/2012/EC concerning particular requirements with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin<br><br>☐ 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) | |

# III. 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<br>Specify the substances and justify their addition |
| K | Presence of software<br>- Use<br>- Production<br>- Storage of patient data<br>- Existence of connectivity feature | ☐ yes ☐ no<br>Free text field<br>Free text field<br>☐ yes ☐ no<br>☐ 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 |

# IV. NON-CLINICAL EVALUATION

## IV-1. Non-clinical recommendations

| | |
|---|---|
| Non-clinical evaluation status | Select an item |
| ☐ EN ISO 10993 series<br>☐ Chemical characterisation performed<br>☐ Biological risk assessment<br>☐ Other | Specify<br>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 |

# V. CLINICAL EVALUATION

| | | |
|---|---|---|
| | **Clinical development strategy**<br>☐ Clinical investigations on the MD/performance studies on the IVDMD<br>☐ Equivalence<br>☐ 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<br>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):<br>(Any divergence must be justified) | |
| b | Risk management strategy | |

# VI. 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: | |

# VII. 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:<br>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<br>- Certification obtained<br>- Composition of subcontracted steps<br>- Consultant used |

## VII-3. Market presence

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

# VIII. 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** | |

143/147, boulevard Anatole France
F-93285 Saint-Denis Cedex
Tél. : +33 (0) 1 55 87 30 00
@ansm

ansm.sante.fr