**Annex 14. UNFPA Questionnaire   
for In vitro Diagnostic products**

# Part I. Submitter and Manufacturer Information

## Submitter details

1.1.1 Name of submitter: Click or tap here to enter text.

1.1.2 Address: Click or tap here to enter text.

1.1.3 Contact person’s name: Click or tap here to enter text.  
1.14 Email: Click or tap here to enter text.  
1.1.5 Phone: Click or tap here to enter text.

1.1.6 Status of the submitter:

Legal manufacturer Yes ☐ No ☐  
 or

Distributor – Trader Yes ☐ No ☐

## Legal manufacturer details

|  |  |  |
| --- | --- | --- |
| 1.2.1 Name of manufacturer | Click or tap here to enter text. | |
| 1.2.2 Manufacturer physical address | Street Name and No.: Click or tap here to enter text. | |
| City: Click here to enter text. | |
| Postcode: Click here to enter text. | Country: Click here to enter text. |
| 1.2.3 Manufacturer postal address | Street Name and No.: Click here to enter text. | |
| Postal Office Box No.: Click here to enter text. | |
| City: Click here to enter text. | |
| Postcode: Click here to enter text. | Country: Click here to enter text. |
| 1.2.4 Manufacturer telephone | Click here to enter text. | |
| 1.2.5 Manufacturer email & web address | Click here to enter text. | |
| 1.2.6 Name of parent company | Click here to enter text. | |
| 1.2.7 List of all manufacturing  sites (subcontractor)/addresses | Click here to enter text. | |
| 1.2.8 Type work conducted by subcontractor e.g final assembly, final sterilization, sub part manufacturing is done by other party than 1.2) | Click here to enter text. | |
| 1.2.9 Date of last inspection of the manufacturer | Click here to enter text. | |

# 

# Part II. Product Information

# Product name and product code

|  |  |  |  |
| --- | --- | --- | --- |
| 2.1.1 Product name: Click or tap here to enter text.2.1.2 Full product name: Click or tap here to enter text. | | | |
| 2.1.3 Provide Test kit configurations, the product code for each kit size and accessories submitted for UNFPA evaluation: Click here to enter text. | | | |
| 2.1.3.a Kit(s) Configuration (s), of components and their quantities (other items which are not IVD MDs but are included to be used in combination with the IVD) | 2.1.3.b Product code | 2.1.3.c Type of Component | 2.1.3.d Description of Components of the IVD and non IVDs indicate xx vial/device/bottle (xx volume) |
| i) | i) | i) | i) |
| ii) | ii) | ii) | ii) |
| iii) | iii) | iii) | iii) |
| iv) | iv) | iv) | iv) |
| v) | v) | v) | v) |
| vi) | vi) | vi) | vi) |
| 2.1.4 Other Accessories/ components/ materials required but not provided (e.g., sample racks, reagent vessels, buffers etc.) | | | |
| 2.1.4.a Name of Accessory and quantities | 2.1.4.b Product code/catalogue number | 2.1.4.c Description of Accessories indicate xx vial/device/bottle (xx volume) | 2.1.4.d Type of Accessories |
| i) |  |  |  |
| ii) |  |  |  |
| iii) |  |  |  |

## 

|  |  |
| --- | --- |
| 2.2 Device classification (specify the related regulation, e.g. MDD, FDA, Other) | Click here to enter text. |

## 2.3 Product utilization

|  |  |
| --- | --- |
| 2.3.1 Intended use/ purpose |  |
| 2.3.2 Population being tested |  |
| 2.3.3 Intended user (lay person or professional) |  |
|  |  |

# Part III. Product – Disease Category, Analyte and Method

## 3.1 Disease category, type of analyte and IVD method of analysis

|  |  |
| --- | --- |
| 3.1.1 Disease category (the specific disorder, condition or risk factor of interest that it is intended to detect, define or differentiate) | Click here to enter text. |
| 3.1.2 Analyte - (Name and type of analyte molecule: Antibody, Antigen, NA, etc.) | Click here to enter text. |
| 3.1.3 IVD method of analysis | Click here to enter text. |
| 3.1.4 IVD function (e.g., screening, monitoring, diagnosis or aid to diagnosis) | Click here to enter text. |

## 3.2 Specimen or sample type

|  |  |
| --- | --- |
| 3.2.1 Select the specimen type(s) to be used with the product | |
| **☐** Serum | **☐** Plasma |
| **☐** Venous whole blood | **☐** Capillary whole blood |
| **☐** Oral fluid | **☐** Dried blood spot |
| **☐** Urine | **☐** Stool |
| Other: Click here to enter text. | |

# Part IV. Regulatory and Commercial Status of the Product

|  |  |  |
| --- | --- | --- |
| 4.1 Is the product WHO prequalified? | **☐** Yes | Start Date: Click here to enter text. Expiry Date: Click here to enter text. |
| **☐** No | |
| 4.2Has the product undergone one of the following 1) a WHO Emergency Use Evaluation and Listing of IVDs (EUAL), 2) an US FDA Emergency Use of Medical Products and Related Authorities (EUA), 3) an approval process from Stringent Regulatory Authority (SRA) designated by Global Harmonization Task Force (GHFT) Competent Authority. IMDRF | **☐** Yes | Name: Click here to enter text. Start Date: Click here to enter text. Expiry Date: Click here to enter text. |
| **☐** No | |
| 4.3Is the product for “Research use only” or “For export only”? | **☐** Yes | |
| **☐** No | |
| 4.4 Is the IVD device considered a humanitarian use device (HUD) and applying for marketing approval through a humanitarian device exemption (HDE)? | **☐** Yes | |
| **☐** No | |

|  |  |  |
| --- | --- | --- |
| 4.5 Provide details of any other current regulatory approvals for this product (Do not include ISO 13485 certification details here. This is covered later) | | |
| Name of regulatory authority/jurisdiction | Type of regulatory approval | Product name  Product code  Period of approval:  Start (DD/MM/YY) -  Expiry (DD/MM/YY) |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |
|  |  |  |
|  |  |  |

## 4.6 Is the product CE marked?

## ☐ Yes ☐No Nature of the EC certification (IVD 98/79/EEC, name annexes): Click here to enter text.

## Identification of the Notified Body (+ identification number): Click here to enter text.

## 

## 4.7 Is the product FDA approved?

## ☐ Yes ☐No

If the device is “510k cleared”, indicate the 510k clearance #: Click here to enter text.

If the device is “PMA cleared”, indicate the PMA clearance #: Click here to enter text.

## 4.8 Is the product approved by any other IMDRF founding members?

## ☐ Yes ☐No

Nature of certification, (number, name, annexes): Click here to enter text.

Identification of the Notified Body (+ identification number): Click here to enter text.

## 4.9 Is the product approved by National Regulatory Agency?

☐ Yes ☐No

Nature of the approval/certification: Click here to enter text.

Name of the National Regulatory Agency: Click here to enter text.

# Part V. Manufacturer – Quality Management System

## 5.1 Legal Manufacturer

ISO 13485 Yes ☐ No ☐

* 1. Certification body and number: Click here to enter text.
  2. Expiration date: Click here to enter text.

ISO 9001 Yes ☐ No ☐

* 1. Certification body and number: Click here to enter text.
  2. Expiration date: Click here to enter text.

FDA CFR 21 (820)

Other Notified body certification?

Certificate of free sale Yes ☐ No ☐

## Submitter (if the submitter is not the legal manufacturer)

# ISO 13485 Yes ☐ No ☐

* 1. Certification body and number: Click here to enter text.
  2. Expiration date: Click here to enter text.

ISO 9001 Yes ☐ No ☐

* 1. Certification body and number: Click here to enter text.
  2. Expiration date: Click here to enter text.

# Part VI. Product –Safety, efficacy, Operation

## 6.1 Risk Analysis

|  |  |  |  |
| --- | --- | --- | --- |
| **6.1.1 ISO 14971**:2012 considerations to show analysis has taken place for products sold in the EU minimizing risk via: post surveillance, compliant history, clinical experience test results, patient and user safety, environment impact. Annex H of ISO 14971. | | | |
| **☐** Risk analyses as per Intended Uses | **☐** Clinical and biological safety | | **☐** Suitability of packaging |
| **6.1.2 Performance Evaluation** | | | |
| ☐ Performance | ☐ Specificity | | ☐ Radio of False to true results |
| ☐ Sensitivity | ☐ Limit of Detection | | ☐ Support Scientific literature |
| 6.1.3 Common Technical Specifications | | | |
| Performance evaluation of product | | **Performance evaluation performed by LAYMAN** | |
| ☐☐ Yes ☐No | |

**Note: Performance evaluation should have been performed by Layman**

## 6.2 Stability studies

|  |
| --- |
| 6.2.1. Describe any stability studies duration and conditions applicable to the product:  Click here to enter text. |

**Note:** Include stability studies data, 3 batches.

## 

## 6.3 Transport, storage and operating temperatures

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 6.3.1 List transport, storage and operating temperatures and shelf life | | | | | |
| Product name  (If more than one box, provide the name for each reagent box) | Transport  temperature range  (min °C - max °C) | Storage temperature range  (min °C -max °C) | Operating temperature range  (min °C - max °C) | Shelf-life upon manufacture (months) | Indicative shelf life upon delivery (months) |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
|  |  |  |  |  |  |
| 6.3.2. Describe any other storage conditions that are applicable to this product:  Click here to enter text. | | | | | |

## 6.4 Labeling, instruction for use and packaging

|  |
| --- |
| 6.4.1 State each component and include samples of labels, primary & secondary packaging, Instruction for use etc. where applicable, sterile or single use items et. |
|
| i) |
| ii) |
| iii) |
| iv) |

# Part VII. Environmental Management System

## 

1. ISO 14001 (Environment) Yes ☐ No ☐
   1. Certification body and number: Click here to enter text.
   2. Expiration date: Click here to enter text.

2. ISO 50001 (Energy Management) Yes ☐ No ☐

* 1. Certification body and number: Click here to enter text.
  2. Expiration date: Click here to enter text.

# Part VIII. Other requirements

## 

|  |
| --- |
| 8.1 State each components’ instructions, information and considerations under the following: |
|
| 8.1.1 Reusable products |
| 8.1.2 Training and support |
| 8.1.3 Warranty |
| 8.1.4 Electrical devices |
| 8.1.5 Disposal of the device |

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# Part IX. Commitment and authorization

## 9.1 Commitment

I, the undersigned, \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ acting as responsible for the company \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,

certify that the information provided (above) is correct and true,

**☐** and I certify that the product offered is identical in all aspects of manufacturing and quality to that marketed in \_\_\_\_\_\_\_\_\_\_\_\_\_\_ (*country of origin*), including disease category type, intended use, intended population, specimen type, method and site of manufacture, sources of materials, quality control of the product and starting material, packaging, shelf-life and product information.

**☐** and I certify that the product offered is identical to that marketed in *(name of country)*, except:

(e.g., state the stipulated exception)

If any changes occur to the information after the submission of this product questionnaire, the manufacturer/supplier undertakes to provide the relevant update as soon as possible.

Date: Signature:

## 9.2 Power of attorney

The manufacturer authorizes a distributor to submit the questionnaire

Date: Signature:

Distributor (Signed by Distributor for Manufacturer under power of attorney)

Please provide a copy of the power of attorney.

# Part X. Checklist of Required Documentation

Documents to be submitted (**where applicable**) must be true and valid copies. All documents submitted must be in English or be accompanied with certified translation.

☐ Copy of manufacturing license

☐ Letter of authorization to act on behalf of manufacturer if submission is not from the manufacturer

☐ Copy of ISO 9001 certificate (for manufacturer and for trader)

☐ Copy of ISO 13485 certificate (for manufacturer and for trader)

☐ Complete and detailed technical specifications of the product (incl. manufacturer’s product code)

☐ Proof of WHO prequalification (If available, or other similar)

☐ CE certificate (additionally for EC class III items EC Design Dossier)

☐ Declaration of conformity (signed and dated, according to ISO 17050, specifying the relevant directives, regulations and standards, and attaching copy of certificates)

☐ Manufacturer’s EC Representative (EC Rep) contact details and country information

☐ FDA 510k Premarket approval device letter/ Device licence (Australia, Japan, Canada)

☐ Evidence that product has been sold to Europe or U.S. or other large market areas with strong regulatory systems.

☐ Photo of the product and packaging (at various angles if necessary).

☐ Technical Sheet of the IVD product.

☐ Evidence of clinical studies to all but class I non-sterile, non-measuring medical devices: e.g. a copy of study results

☐ Product technical data sheet

☐ Photos of the product, packaging and labelling at various angles if necessary

☐ Trilingual En/Fr/Es version of the instructions-for-use for the IVD product. Instructions-for-use are also known as a package insert (where applicable).

☐ A certificate of analysis for at least one recently released batch.

☐ Stability studies of at least 3 batches

☐ User, installation and/or assembly manual, if applicable

☐ Service/repair (after sale) services with contact details, if applicable

☐ Information on cleaning, disinfecting and sterilization methods (for reusable devices only)

☐ Certificates for product-specific safety standards, such as ISO 10993-1.

☐ Certificate for sterilization process, such as ISO 17665 (Steam sterilization), ISO 11135 (ETO sterilization), ISO 11137 (Gamma Irradiation), or other equivalent.

☐ Manufacturer’s Post-market study report from 3 last years

☐ Quality Assurance process (for the manufacturer and/or for the trader)

☐ Specify any other documentation provided (e.g. any test results or relevant standards):

☐ ISO 14001. If not available, a signed commitment letter from a manufacturer

☐ Other relevant certificates related to Environmental and/or Energy management, such as ISO 50001, or FSC certificates for the carton and paper used in packaging (for manufacturer and for trader).

☐ Manufacturer’s copy of the latest audit report (audited by a European health product distributor)

☐ Copy of third-party laboratory test reports, if available (Laboratory name and ISO 17025 accreditation status), if applicable.

\*) UNFPA accepts the versions of currently active standards, which are recognized by the International Organization for Standardization at the time of document submission.