**Annex III**

**Questionnaire for Menstrual Health management (MHM) products**

*All documents submitted must be in English or be accompanied with certified translation.*

**PART I – Submitter and manufacturer information**

**Submitter:**

Name of submitter: Click here to enter text.
Address: Click here to enter text.
Contact person’s name: Click here to enter text.
Email: Click here to enter text.
Phone: Click here to enter text.

Status of the submitter:

Legal manufacturer Yes ☐ No ☐
 or

Distributor – Trader Yes ☐ No ☐

 **Legal manufacturer:**

Name of manufacturer: Click here to enter text.
Country: Click here to enter text.
Address (office): Click here to enter text.
Address (manufacturing site(s)): Click here to enter text.
Contact person’s name: Click here to enter text.
Email: Click here to enter text.
Phone: Click here to enter text.

**PART II – Product identification**

**Bid item** (Bid item number and short description)Click here to enter text.

**Product Identification** (Product name, Brand name, Product Code)**:**Click here to enter text.

**Intended use / purpose:** Click here to enter text.

**Product details** (Product name, Description, intended use, material of construction, dimensions, etc.)**:**Click here to enter text.

**Product classification** (specify the applicable regulation, e.g. **EU 93/42/EEC** directive, Annex # Rule#, FDA medical device, EU/GPSD, cosmetic and toiletry, Other country specific regulations etc.)

Specify, whichever is applicable. Please mention as “medical device” if the manufacturer is claiming the MHM product as a medical device): Click here to enter text.

**Other country specific regulations** (specify details): Click here to enter text.

**Nomenclature code** (if known – specify GMDN, UMDNS or other): Click here to enter text.

# Part III – Quality Management System Certification

**Legal Manufacturer:**

1. ISO 9001 Yes ☐ No ☐
	1. Certification body: Click here to enter text.
	2. Expiration date: Click here to enter text.
2. ISO 13485-2016 Yes ☐ No ☐
	1. Certification body: Click here to enter text.
	2. Expiration date: Click here to enter text.
3. ISO 14001 or plans for this Yes ☐ No ☐
	1. Certification body: Click here to enter text.
	2. Expiration date: Click here to enter text.
4. ISO 50001 or plans for this Yes ☐ No ☐
	1. Certification body: Click here to enter text.
	2. Expiration date: Click here to enter text.

**If the manufacturing processes are subcontracted:**

|  |  |  |
| --- | --- | --- |
| **Subcontracted activity / process** | **Name / address of the subcontractor** | **QMS certification of the subcontractor** |
| 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. |
| Click here to enter text. | Click here to enter text. | Click here to enter text. |

**Submitter** (if the submitter is not the legal manufacturer):

1. ISO 9001 Yes ☐ No ☐
	1. Certification body: Click here to enter text.
	2. Expiration date: Click here to enter text.
2. ISO 13485-2016 Yes ☐ No ☐
	1. Certification body: Click here to enter text.
	2. Expiration date: Click here to enter text.

## Part IV – Regulatory certification

Is the **product CE marked with notified body number?** Yes ☐ No ☐

Is the **product CE self-certified?** Yes ☐ No ☐

Has the manufacturer completed the conformity checks to applicable standard, creation of a technical file and Declaration of conformity for **CE self-certification?**

 Yes ☐ No ☐

Is the product **FDA** approved/compliant? Yes ☐ No ☐

Applicable FDA section: Click here to enter text.

Other **Regulatory** clearance / registration (specify Canada, Japan, Australia, USA, European union etc.): Click here to enter text.

 Applicable regulation: Click here to enter text.

 Certification / license number: Click here to enter text.

## Part V – Compliance to technical standards

If the declaration of compliance is based on report(s) issued by an independent testing laboratory, the reference of the test report must be indicated

|  |  |  |  |
| --- | --- | --- | --- |
| **Applicable standard name** | **Fully or partially applied** | **Identification of the Testing laboratories, where used** | **Test report reference** |
| Click here to enter text. | Click here to enter text. | Click here to enter text. | Click here to enter text. |
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## Part VI – Other information

### Safe disposal, Training, Decontamination

Specify instructions for safe disposal: Click here to enter text.

Specify any online demonstration modules are available: Click here to enter text.

Specify decontamination method for reusable MHM products, e.g. menstrual cup: Click here to enter text.

**Checklist of Required documentation:**Documents to be submitted must be true and valid copies.

**Part I – Submitter and manufacturer information**

☐ Copy of manufacturing licence

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

**Part II – Product Identification**

☐ Complete and detailed technical specifications of the product (incl. manufacturer’s product code). Product technical data sheet / product technical file

☐ Photos of the product, primary and secondary packaging with labelling. In case of finished product in packaging are not available, please provide approved artwork.

☐ Instruction for use in English, Spanish, Arabic and French

☐ Information on cleaning, disinfecting and sterilization methods (for reusable products such as menstrual cup)

☐ Evidence of benchmark testing with market samples for functional properties (provide a copy of the test results), if available

☐ Evidence of biocompatibility as per applicable sections of ISO 10993 test standards and bioburden testing (provide a copy of the test results)

**Part III – Quality Management System Certification**

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

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

☐ Other certifications such as ISO 14001, ISO 50001, or FSC certificates, if available.

**Part IV – Regulatory certification**

☐ CE certificate (Self certified / CE marking with notified body, whichever is applicable)

☐ 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, if applicable

☐ FDA compliance, if applicable

☐ Compliance to other regulatory certifications such as REACH certification, RoHs certification.

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

**Part V – Compliance to technical standards**

☐ Proof for conformance to product-specific standards regarding safety, functional performance and other product specific claims, as applicable

☐ Manufacturer’s Post-market study report for the last 3 years, or as applicable for a new manufacturer

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

**Part VI – Other information**

Any documents for safe disposal, training, decontamination, as applicable