**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