**Questionnaire for dignity kit items**

*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**

**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). Add rows if you need more.

|  |  |  |  |
| --- | --- | --- | --- |
| **Item name** | **consumer/personal care and cosmetics/clothing/infection prevention control/electrical & battery operated products /infection prevention control/ medical device/ any other specify** | **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** | **Product certifications if any** |
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\*If the item is electrical and battery operated, use the ‘UNFPA Questionnaire for Electrical or Battery Operated Equipment\_v3’

Specify, whichever is applicable.

**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 or private labelled:**

|  |  |  |
| --- | --- | --- |
| **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.
   3. Whether the product under offer is included in the ISO 13485: Click here to enter text.

## Part IV – Regulatory certification

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

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

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  NA

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

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.

**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 – Proof of compliance to product specification to be accompanied with bid response**

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

If the item comes in contact with human body, a declaration (signed and dated) from the manufacturer shall be submitted which clearly states that the “item is fit for human use and that no recycled, or skin harmful materials are being used in the manufacturing process”.

 Photos of the product from all four sides or from various angles shall be submitted.

Photos of the primary and secondary packaging from all four sides with labelling clearly visible shall be submitted. In case of finished product in packaging are not available, please provide approved artwork.

 Instruction for use in English, Spanish, Arabic and French. Preferable to have a video on usage for relevant products, wherever appropriate (eg. Head cover, skirt etc)

Information on cleaning, if relevant to the item under offer shall be provided.

Evidence of compliance to applicable standards (provide a copy of the test results), certificate of analysis etc.

**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**

Product certificates from authorised certification bodies ensuring safety, legality, and quality of products shall be submitted in one or many of the following wats as detailed below.

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.

Other certifications relevant for the items under offer such as Oeko-Tex certification, Ecolabel etc from authorised certification bodies, if available.

CE certificate (Self certified / CE marking with notified body, if applicable)

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

Manufacturer’s EC Representative (EC Rep) contact details and country information, if applicable

FDA compliance, if applicable

**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