



DECLARATION FORM – FITNESS FOR USE AND QUALITY OF THE  
PRODUCT

Commission Decision (EU) establishing the EU Ecolabel criteria for absorbent hygiene products and for reusable menstrual cups

## Declaration for the fitness for use and quality of the product of the reusable menstrual cup

This declaration is to be filled in by the applicant or by the supplier of the reusable menstrual cup. The declaration shall be based on the best of the applicant's/supplier's knowledge at the time of declaring.

Applicant/supplier name \_\_\_\_\_

Applicant/supplier address \_\_\_\_\_

Applicant/supplier of:

(please specify) \_\_\_\_\_

Name of the reusable menstrual cup: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Type of the reusable menstrual cup: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

I declare that I will keep the competent body informed if any changes to our products or processes are made which influence the validity of this declaration

### Criterion 8: Fitness for use and quality of the product

I declare that the effectiveness/quality of the reusable menstrual cup(s) is satisfactory and at least equivalent to that of products already on the market. Fitness-for-use has been tested with respect to the characteristics outlined in the following table:

Date:

July 2023

Version 1



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Characteristics	Testing practice required (performance threshold)	Test results and evaluation (report to be attached)
U1. Leakage protection	Consumer panel test (80 % of the consumers testing the product shall rate the performance as satisfactory)	<input type="checkbox"/>
U2. Fit and comfort		<input type="checkbox"/>
U3. Overall performance		<input type="checkbox"/>

*It is mandatory to submit supporting information (i.e. test report for each in-use test outlined in the table above, describing test methods, test results and data used)*

*I attach supporting information.*

I declare that the effectiveness/quality of the reusable menstrual cup(s) is satisfactory and at least equivalent to that of products already on the market. Technical fitness-for-use has been tested with respect to the characteristics outlined in the table below:

Characteristics	Testing practice required	Test results and evaluation (report to be attached)
T1. Biocompatibility	No relevant biological effects in the studies performed for cytotoxicity, pyrogenicity, sensitization, dermal irritation and implantation (90 days) as indicated by ISO 10993.  Alternatively compliance with USP Class VI standard (acute systemic toxicity, intracutaneous toxicity and implantation test) could be reported.	<input type="checkbox"/>

*It is mandatory to submit supporting information (i.e. test report the technical test outlined in the table above, describing test methods, test results and data used)*

*I attach supporting information.*



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I, the undersigned, hereby declare that all the documents provided to demonstrate the accomplishment with the criteria are true and correspond to reality.

Place and date:	Company name/stamp:
Responsible person, phone number and e-mail:	Signature of responsible person:

Date:

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