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:

Characteristics	Testing practice required (performance treshold)	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)	☐
U2. Fit and comfort		☐
U3. Overall performance		☐

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.	☐

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.*

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: