



Manufacturer's Product Statement

Product description:

The Mooncup is a reusable menstrual cup for the insertion into the vagina to collect menstrual flow during a woman's monthly menstruation.

Material:

The Mooncup is moulded from a single piece of medical grade silicone rubber material which has been certified by the material supplier, Wacker Chemie GmbH as being tested to the requirements of ISO 10993 – 1 for cytotoxicity, haemolysis, pyrogenicity, sensitisation, dermal irritation and implantation (90 days).

Product approval:

The Mooncup is not considered a Medical Device in Europe and is not subject to E U directives beyond general product safety standards. However in the USA the Mooncup is considered a Medical Device and holds FDA market approval as follows:

Number: K060852
Trade/Device Name: 21 CFR 884.5400
Regulation Name: Menstrual Cup
Regulatory Class: II
Product Code: HHE
Dated: December 8, 2006

Manufacture: The Mooncup is manufactured in the UK for Mooncup Ltd.