

Therapeutic Goods (Standard for Menstrual Cups) Order 2018 (Therapeutic Goods Order 99)

I, Benjamin Noyen, as delegate for the Minister for Health, make the following order.

Dated 31 October 2018

(Signed by)

Benjamin Noyen

Acting First Assistant Secretary

Medical Devices and Product Quality Division

Department of Health

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1 Name

 (1) This instrument is the *Therapeutic Goods (Standard for Menstrual Cups) Order 2018*.

 (2) This instrument may also be cited as Therapeutic Goods Order 99, or TGO 99.

2 Commencement

 (1) Each provision of this instrument specified in column 1 of the table commences, or is taken to have commenced, in accordance with column 2 of the table. Any other statement in column 2 has effect according to its terms.

| Commencement information |
| --- |
| Column 1 | Column 2 | Column 3 |
| Provisions | Commencement | Date/Details |
| 1. The whole of this instrument | The day after this instrument is registered. |  |

Note: This table relates only to the provisions of this instrument as originally made. It will not be amended to deal with any later amendments of this instrument.

 (2) Any information in column 3 of the table is not part of this instrument. Information may be inserted in this column, or information in it may be edited, in any published version of this instrument.

3 Authority

 This instrument is made under subsection 10(1) of the Act.

4 Definitions

Note: A number of expressions used in this instrument are defined in definitions section of the Act, including the following:

(a) Secretary;

(b) sponsor;

(c) therapeutic goods.

 In this instrument:

***Act*** means the *Therapeutic Goods Act 1989*.

***batch*** means a quantity of menstrual cups which, as far as practicable, consists of material or items of the same type, grade, class and composition, which have been manufactured under essentially the same conditions within a specified period of time.

***Menstrual cup*** means a product made from permissible raw materials that is inserted into the vagina and used to collect or capture menstrual discharge.

***Packaging*** means any of the following layers:

* unit pack (the pack enclosing a single menstrual cup);
* primary pack (the pack containing one or more unit packs);
* supply pack (the pack that is supplied to the consumer). The supply pack may consist of a single primary pack, or may contain one or more primary packs; or

5 Application

 (1) The requirements set out in this instrument apply to all therapeutic goods that are menstrual cups.

6 Permissible Raw Materials

 (1) Menstrual cups must be manufactured from materials that are suitable for the intended purpose of the menstrual cup.

 (2) Menstrual cups must not contain ingredients in sufficient concentration to cause a toxic or irritant reaction when used as directed.

**7 Design Requirements**

 (1) The surface and shape of a menstrual cup must be smooth and designed to minimise the risk of trauma.

**8 Packaging**

 (1) The following requirements apply to the packaging for menstrual cups:

1. the menstrual cup must be packed in a closed unit pack that is capable of maintaining the menstrual cup’s quality until the unit pack is opened by the consumer; and
2. the unit pack must be packed in a primary pack which is sufficiently robust to maintain the integrity of, and protect, the menstrual cup during normal transport and storage; and
3. the primary pack must be designed, overwrapped or sealed in such a manner that tampering will be easily detected.

**9 Labelling**

 (1) The primary pack must be permanently and legibly marked with the following information:

 (a) words identifying the brand name;

 (b) the name and address of the manufacturer or supplier;

 (c) if the primary pack contains more than one unit pack, the name and quantity of all the menstrual cups within the primary pack;

 (d) the batch number of the menstrual cup(s), identified with the use of the words “Batch No.” or “Lot No.”;

 (e) words identifying the size (if applicable) of the menstrual cup; and

 (f) the following warning in letters with a height of not less than 1mm:

 “IMPORTANT: Menstrual cups have been associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and keep the enclosed information.”

**10 Information to be supplied with menstrual cups**

 (1) The following information must be supplied with the menstrual cup, in a form that is legible and accessible to the consumer:

1. the manufacturer’s or supplier’s identifying information, including their name and address;
2. an information leaflet containing the following information:
	1. detailed instructions for use, including the need for hygiene and care in insertion;
	2. a limit to the duration of use, not exceeding 8 hours;
	3. detailed instructions for cleaning and maintaining the integrity of the menstrual cup;
	4. a notification that the menstrual cup is not supplied in a sterile state;
	5. information about Toxic Shock Syndrome, noting that while it is rarely associated with the use of menstrual cups, it can still occur;
	6. the following warning in letters with a height of not less than 1mm:

 “IMPORTANT: Menstrual cups have been associated with Toxic Shock Syndrome (TSS). TSS is a rare but serious disease that may cause death. Read and keep the enclosed information.”