LIVINGSTONE INTERNATIONAL PTY LTD
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Issue Date: 18/02/2021
Last Revision Date: 04/01/2024
Superseded Date: 18/02/2021
Version Number: 02

# SAFETY DATA SHEET

**Product Code: TOOTHETTE6070**



## SECTION 1 PRODUCT IDENTIFICATION

| | |
|---|---|
| **Product Name** | Livingstone Toothette Oral Mouth Swabs |
| **Product Type** | Single Device Product |
| **GMDN** | 48037 Oral care swab, non-sterile |
| **Functional Description** | Not included on record |
| **Intended Purpose** | A foam headed oral Swab designed to be used wet and/or with a cleaning solution or paste to clean the teeth and oral cavity. |
| **Specific Conditions** | No specific conditions included on record. |

## SECTION 2 HAZARD IDENTIFICATION

No information available

## SECTION 3 COMPOSITION/INFORMATION ON INGREDIENTS

No information available

## SECTION 4 FIRST AID MEASURES

No information available

## SECTION 5 FIRE FIGHTING MEASURES

No information available

## SECTION 6 ACCIDENTAL RELEASE MEASURES

No information available

## SECTION 7 HANDLING AND STORAGE

No information available

## SECTION 8 EXPOSURE CONTROLS/PERSONAL PROTECTION

No information available

## SECTION 9 PHYSICAL/CHEMICAL PROPERTIES

No information available

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## SECTION 10 STABILITY AND REACTIVITY

No information available

## SECTION 11 TOXICOLOGICAL INFORMATION

No information available

## SECTION 12 ECOLOGICAL INFORMATION

No information available

## SECTION 13 DISPOSAL CONSIDERATIONS

No information available

## SECTION 14 TRANSPORT INFORMATION

No information available

## SECTION 15 REGULATORY INFORMATION

No information available

## SECTION 16 OTHER INFORMATION

**Conditions**

The automatic conditions applicable to the inclusion of all kinds of medical devices in the Register are as specified in section 41 FN of the Therapeutic Goods Act 1989.

The standard conditions that are imposed under section 41 FO of the Therapeutic Goods Act 1989 when kinds of medical devices are included in the Register are as set out in the following paragraphs.

For a medical device included in the Register under Chapter 4 and imported into Australia, the Sponsor must ensure that information about the Sponsor is provided in such a way as to allow the sponsor to be identified.

Each sponsor shall retain records of the distribution of all of the sponsor's medical devices included in the Register under Chapter 4. In the case of records relating to a Class AIMD medical device, Class III medical device, or Class IIb medical device that is an implantable medical device, the distribution records shall be retained for a minimum period of 10 years. In the case of records relating to any other device, the distribution records shall be retained for a minimum period of 5 years.

The sponsor of a medical device included in the Register under Chapter 4 shall keep an up to date log of information of the kind specified in Regulation 5.8.

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It is a condition of inclusion in the ARTG that the sponsor of a medical device that is an AIMD, Class Ill or implantable Class lib provides three consecutive annual reports to the Head of the Office of Product Review, Therapeutic Goods Administration following inclusion of the device in the ARTG (as specified in 5.8 of the regulations). Annual reports are due on 1 October each year. Reports should be for the period 1 July to 30 June. The first report following the date of inclusion in the ARTG must be for a period of at least six months but no longer than 18 months. Subsequent reports are to be provided on 1 October for a further 2 years. The annual report must include all complaints and adverse events received by the manufacturer relating to problems with the use of the device that have been received by them over the year. For orthopaedic implant prosthesis that have been re-classified from Class lib to Class 111m edical devices, annual report information must be submitted if the device meets either of the following criteria: I.The device was subject to a TGA application audit based on revision rate when the device transitioned from Class llb to Class 111a; nd/or II.No devices were supplied to the Australian marketplace before 30 June 2012. As per the standard automatic condition, annual reports should be submitted each year for the first three years of inclusion as a Class Ill medical device on the ARTG.

Where a medical device included in the Register, contains a substance which is included in the Fourth schedule to the Customs (Prohibited Imports) Regulations or the Eighth Schedule to the Customs (Prohibited Exports) Regulations the Sponsor shall, at the time of importation or exportation of the medical device, be in possession of a licence and a permission for importation or exportation of each consignment of the goods as required by those regulations.

A sponsor shall ensure that a medical device within their control is stored and transported in accordance with the instructions and information provided bythe manufacturer.

**Reason for Revision:** To bring to date

## END OF SDS