



Australian Government

Department of Health and Ageing  
Therapeutic Goods Administration

# Australian Register of Therapeutic Goods Certificate

Issued to

**Synthes Australia Pty Ltd**

for approval to supply

**Skin - Synthes Australia Pty Ltd**

**ARTG Identifier** 211608  
**ARTG Start date** 1/07/2013  
**Product Category** Biological Included Class 2  
**Intended Use** 1. Replacement of damaged or inadequate integumental tissue, or reinforcement of soft tissue defects  
 2. Replacement of damaged or inadequate integumental tissue, or reinforcement of soft tissue defects

Manufacturer Details	Address	Manufacturing Steps
Musculoskeletal Transplant Foundation	Suite 300 / 125 May Street Edison, NJ, 08837 United States Of America	Manufacture of Allograft Skin,  Packaging and labelling, Release for supply
Musculoskeletal Transplant Foundation	Suite 300 / 125 May Street Edison, NJ, 08837 United States Of America	Manufacture of Allograft Skin,  Release for supply, Packaging and labelling
Musculoskeletal Transplant Foundation	1232 Mid Valley Drive Jessup, Pennsylvania, 18434-1823 United States Of America	Testing chemical and physical
Musculoskeletal Transplant Foundation	1795-A-Orange Tree Lane Redlands, California, 92374 United States Of America	Storage on site
VRL Laboratories	6665 S Kenton Street Suite 205 Centennial, Colorado, 80111 United States Of America	Virology Screening and Syphilis Testing, NAT Testing for HIV, HCV and HBV
Wuxi Apptec Inc	1265-B Kennestone Circle Marietta, Georgia, 30066 United States Of America	Testing sterility

### ARTG Standard Conditions

The above Biological Included Class 2 has been entered on the Register subject to the following conditions:

No conditions have been recorded against this entry.

### Products Covered by This Entry

#### 1. FlexHD

Container Type	Container Material	Container Condition	Container Closure	Shelf Life Time	Shelf Life Temperature	Shelf Life Conditions
----------------	--------------------	---------------------	-------------------	-----------------	------------------------	-----------------------

Bag	Other composite material	Not recorded	Not recorded	3 Years	Store between 15-30 degrees Celsius	Store at room temperature
-----	--------------------------	--------------	--------------	---------	-------------------------------------	---------------------------

### Product Specific Conditions

- 2) Approval for changes or variations in respect of any information concerning the therapeutic good that would have been relevant to a decision to include the goods in the ARTG, must be the Secretary, or the Secretary's delegate. This includes information on the formulation of the goods or other aspects of their manufacture, and the labelling of the goods. The change or variation shall not be implemented until approved by the Secretary,
- 1) The therapeutic good must be supplied with the Product Insert at Attachment 4. Any proposed changed to the approved text of the Product Insert must be submitted to, be approved by, the TGA prior to distribution,
- 5) As part of routine Pharmacovigilance the submission of Periodic Safety Update Reports (PSURs) are required. The reports must meet the requirements for Periodic Safety Update Reports as described in the European Medicines Agency's Guideline on Good Pharmacovigilance Practices (GVP) Module VII-Periodic Safety Update Report. Each report must have been prepared within seventy calendar days of the data lock point for that report, as required by the European Medicines Agency's Guideline for PSUR's covering intervals up to 12 months (including intervals of exactly 12 months). Unless agreed separately between the Sponsor who is the recipient of the approval and the TGA, the first report must be submitted to TGA no later than 15 calendar months after the date of this letter. The subsequent reports must be submitted no less frequently than annually from the date of the first submitted report until the period covered by such reports is not less than three years from the date of this approval letter. No fewer than three annual reports are required. The annual submission may be made up of two PSURs each covering six months. If the sponsor wishes, the six monthly reports may be submitted separately as they become available,
- 4) The actual date of commencement of supply should be notified to the Director, Biological Sciences Section of the TGA. Should it be decided not to proceed to supply the therapeutic good in Australia, notification to this effect must be provided to the Director, Biological Sciences Section of the TGA. A copy of the notification form has been provided as Attachment 5,
- 6) The sponsor must comply with any reporting requirements that are prescribed. For the purpose of this condition it is a requirement that the sponsor maintains documented procedures for traceability of products from donor to recipient and vice versa, and complies with the reporting requirements set out in section 32 DQ of the Act. Specifically, the Sponsor must inform the Secretary in writing, within the periods specified in the regulations, of: a) information that contradicts information already given by the person under this Act in relation to the biological (including information given about the quality, safety or efficacy of the biological): information that indicates that the use of the biological in accordance with the recommendations for its use may have an unintended harmful effect and: information that indicates that the biological, when used in accordance with the recommendations for its use, may not be as effective as the application for inclusion of the biological in the Register or information already given by the person under this Act suggests. Note: Section 32DQ of the Act also provides for penalties where the Sponsor of the goods fails to inform the Secretary in writing of the matters set out in section 32DQ.,
- 3) Promotional material relating to the therapeutic good must comply with the requirements outlined in the Code of Conduct of Medicines Australia, Edition 17 effective 11 January 2013 (<http://medicinesaustralia.com.au/code-of-conduct/>)

### 2. FlexHD Pliable

Container Type	Container Material	Container Condition	Container Closure	Shelf Life Time	Shelf Life Temperature	Shelf Life Conditions
Bag	Other composite material	Not recorded	Not recorded	1 Years	Store between 15-30 degrees Celsius	Store at room temperature

### Product Specific Conditions

- 6) The sponsor must comply with any reporting requirements that are prescribed. For the purpose of this condition it is a requirement that the sponsor maintains documented procedures for traceability of products from donor to recipient and vice versa, and complies with the reporting requirements set out in section 32 DQ of the Act. Specifically, the Sponsor must inform the Secretary in writing, within the periods specified in the regulations, of: a) information that contradicts information already given by the person under this Act in relation to the biological (including information given about the quality, safety or efficacy of the biological): information that indicates that the use of the biological in accordance with the recommendations for its use may have an unintended harmful effect and: information that indicates that the biological, when used in accordance with the recommendations for its use, may not be as effective as the application for inclusion of the biological in the Register or information already given by the person under this Act suggests. Note: Section 32DQ of the Act also provides for penalties where the Sponsor of the goods fails to inform the Secretary in writing of the matters set out in section 32DQ.,
- 5) As part of routine Pharmacovigilance the submission of Periodic Safety Update Reports (PSURs) are required. The reports must meet the requirements for Periodic Safety Update Reports as described in the European Medicines Agency's Guideline on Good Pharmacovigilance Practices (GVP) Module VII-Periodic Safety Update Report. Each report must have been prepared within seventy calendar days of the data lock point for that report, as required by the European Medicines Agency's Guideline for

PSUR's covering intervals up to 12 months (including intervals of exactly 12 months). Unless agreed separately between the Sponsor who is the recipient of the approval and the TGA, the first report must be submitted to TGA no later than 15 calendar months after the date of this letter. The subsequent reports must be submitted no less frequently than annually from the date of the first submitted report until the period covered by such reports is not less than three years from the date of this approval letter. No fewer than three annual reports are required. The annual submission may be made up of two PSURs each covering six months. If the sponsor wishes, the six monthly reports may be submitted separately as they become available,

- 4) The actual date of commencement of supply should be notified to the Director, Biological Sciences Section of the TGA. Should it be decided not to proceed to supply the therapeutic good in Australia, notification to this effect must be provided to the Director, Biological Sciences Section of the TGA. A copy of the notification form has been provided as Attachment 5,
- 2) Approval for changes or variations in respect of any information concerning the therapeutic good that would have been relevant to a decision to include the goods in the ARTG, must be the Secretary, or the Secretary's delegate. This includes information on the formulation of the goods or other aspects of their manufacture, and the labelling of the goods. The change or variation shall not be implemented until approved by the Secretary,
- 1) The therapeutic good must be supplied with the Product Insert at Attachment 4. Any proposed changed to the approved text of the Product Insert must be submitted to, be approved by, the TGA prior to distribution,
- 3) Promotional material relating to the therapeutic good must comply with the requirements outlined in the Code of Conduct of Medicines Australia, Edition 17 effective 11 January 2013 (<http://medicinesaustralia.com.au/code-of-conduct/>)

---

Therapeutic Goods Administration  
PO Box 100, Woden ACT 2606 Australia  
Phone: 1800 020 653  
Email: [info@tga.gov.au](mailto:info@tga.gov.au)

ARTG Identifier: 211608  
ARTG Start Date: 1/07/2013