Australian Government

Department of Health
Therapeutic Goods Administration

Australian Register of Therapeutic Goods Certificate

Issued to

Johnson & Johnson Medical Pty Ltd t/a DePuy Synthes

for approval to supply

Musculoskeletal Tissue - Synthes Australia Pty Ltd

ARTG Identifier	254592
ARTG Start date	12/08/2015
Product Category	Biological Included Class 2
Intended Use	Restoring bone volume or filling voids or gaps in the skeletal system

Manufacturer Details	Address	Manufacturing Steps
Musculoskeletal Transplant Foundation	1795-A-Orange Tree Lane Redlands, California, 92374 United States Of America	Storage
Musculoskeletal Transplant Foundation	1232 Mid Valley Drive Jessup, Pennsylvania, 18434-1823 United States Of America	Storage on site Packaging and labelling Processing
Musculoskeletal Transplant Foundation * Principal Manufacturer	Suite 300 / 125 May Street Edison, NJ, 08837 United States Of America	Packaging and labelling Release for supply Processing Storage on site
Musculoskeletal Transplant Foundation	1175 Mid Valley Drive Olyphant, Pennsylvania, 18447 United States Of America	Storage on site
Steris Isomedix Services	9 Apollo Drive WHIPPANY, NJ, 07981 United States Of America	Sterilization - Gamma Irradiation
Steris Isomedix Services	2500 Commerce Drive Libertyville, Illinois, 60048 United States Of America	Sterilization - Gamma Irradiation
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	2540 Executive Drive St Paul, MN, 55120 United States Of America	Testing biological
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:

· Conditions applicable to all included biologicals as specified in section 32EA of the Act.

Products Covered by This Entry

1. Bone, Morsellised, Freeze dried, Irradiated- L

Container Type	Container Material	Container Condition	Container Closure	Shelf Life Time	Shelf Life Temperature	Shelf Life Conditions
Jar/Can	Other composite material	Not recorded	Not recorded	2 Years	Store between 15-30 degrees Celsius	Do not Freeze

Product Specific Conditions

- 4. If a good that is distributed overseas is the same as a good that is included in the Register and supplied in Australia, any product recall or similar regulatory action taken in relation to the good outside Australia that concerns, or is related to, the quality, safety or efficacy of the good, must be notified to the Secretary by the sponsor of the good as soon as the sponsor becomes aware of the action. For this purpose, the Secretary is taken to have been notified when the information is forwarded to the Post-market Surveillance Branch at the TGA either by email at adr.reports@tga.gov.au or via online report forms provided on the TGA website.
- 3. The actual date of commencement of supply of the good after inclusion under Part 3-2A of the Act must be notified to the Director, Biological Sciences Section of the TGA. Please note the definition of 'supply' in subsection 3(1) of the Act for this purpose.
- 2. The sponsor must keep records of the supply and distribution of the good for a period of ten (10) years after the distribution of the good.
- 1. Any variations or changes to the good cannot be implemented without either the approval of the Secretary under section 9D of the Act to vary the product's entry in the ARTG or through a change to a condition.

Therapeutic Goods Administration
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Phone: 1800 020 653
Email: info@tga.gov.au

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