Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2013-CE-05845-1

Issued to:

Musculoskeletal Transplant Foundation

Manufacturing Site Address:

1232 Mid Valley Drive
Jessup Pennsylvania
United States of America

The Therapeutic Goods Administration, the Competent Authority of Australia, confirms that this manufacturer has been inspected following section 32EA(1) of the *Therapeutic Goods Act 1989* in connection with manufacturers of Biologicals (items made from or containing human cells or human tissues) located outside Australia.

From the knowledge gained during inspection of this manufacturer, the latest of, that was conducted on 20 to 22 April 2015, it is considered that the manufacturer complies with the Good Manufacturing Practice (GMP) requirements of the Australian Code of Good Manufacturing Practice for Human Blood and Tissues (2000).

This certificate reflects the status of the manufacturing site at the time of the inspection noted above. This certificate remains valid until the expiry date provided that re-inspections are conducted as determined by the Therapeutic Goods Administration as the issuing Authority. This certificate should not be relied upon to reflect the compliance status after the expiry date.

EXPIRY DATE: 22 April 2017

ISSUE DATE: 29 February 2016

Name and signature of an authorised person of the Competent Authority of Australia:

Signed: .....

Hongxia Jin
Director, Licensing and Certification
Manufacturing Quality Branch

This certificate is valid only if the security provisions (blue and grey curved dotted lines on the bottom half of each page) are visible.

This certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration.

The authenticity of this certificate may be verified with the Therapeutic Goods Administration as the issuing authority.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 02 6232 8444 Fax: 02 6232 8605 Email: info@tga.gov.au www.tga.gov.au

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MANUFACTURING OPERATIONS

This certificate covers the following steps in the manufacture of therapeutic goods at the manufacturing site address specified above.

Manufacturing Type	Product Category	Manufacturing Step
Human Tissue	Allograft - Bone	Processing Storage on site Packaging and labelling Release for supply
Human Tissue	Not Applicable	Testing - Analytical/Biological

Name and signature of an authorised person of the Competent Authority of Australia:

Signed: .....

Hongxia Jin
Director, Licensing and Certification
Manufacturing Quality Branch

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TGA Health Safety Regulation