Australian Government

Department of Health
Therapeutic Goods Administration

2014/019664

Mr Keith Alderman
Vice President Quality Assurance
Musculoskeletal Transplant Foundation
Suite 300 / 125 May Street
Edison NJ 08837
United States of America

Dear Keith,

Subject: Issue of GMP certificate MI-2013-CE-08888-1

Please find enclosed the GMP certificate for your manufacturing premises.

You may note its changed layout with new security provisions: blue and grey curved dotted lines at the bottom half of each page. These provisions are intended to prevent unauthorised copying as part of a process to introduce issuing certificates electronically in the near future. This will also include using electronic signatures only.

The certificate remains valid only if re-inspections are conducted when scheduled by the Therapeutic Goods Administration. The inspection frequency is not a reflection of the expiry date shown on the certificate but is consistent with the re-inspection frequency applicable to Australian manufacturers of the same class of products.

The Therapeutic Goods Administration will contact the relevant sponsor/s to arrange the re-inspection of your facility.

If you have any queries regarding this certificate, please do not hesitate to ask using the contact details below.

Yours sincerely,

Hongxia Jin
Director – Licensing and Certification
Manufacturing Quality Branch

29 February 2016

Contact: GMP
Email: bcu.act@tga.gov.au Phone: +612 6221 6865 Fax: +612 6232 8426

Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2013-CE-08888-1

Issued to:

Musculoskeletal Transplant Foundation

Manufacturing Site Address:

Suite 300 / 125 May Street
Edison New Jersey
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 13 to 17 April 2015, it is considered that the manufacturer complies with the Australian Code of Good Manufacturing Practice for Human Blood and blood components, human tissues and human cellular therapy products (2013).

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: 17 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

Australian Government

Department of Health
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2013-CE-08888-1

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	Demineralised Bone Matrix (DBM)	Processing Packaging and labelling Storage on site Release for supply
Testing Laboratory	Not Applicable	Testing - Analytical
Human Tissue	Acellular Human Dermal Matrix	Processing Packaging and labelling Storage on site Release for supply

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

TGA Health Safety Regulation