Australian Government

Department of Health
Therapeutic Goods Administration

Mr Keith Alderman
Vice President Quality
Musculoskeletal Transplant Foundation
1175 Mid Valley Drive
Olyphant Pennsylvania 18447

Our Reference: 2014/019698

Dear Mr Alderman,

Subject: Issue of GMP certificate MI-2016-CE-01982-1

Please find enclosed the GMP certificate for your manufacturing premises.

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.

Yours sincerely,

Signed and authorised by

Alyce Maksoud
Senior Inspector
Manufacturing Quality Branch

25 January 2018

Contact: gmp@tga.gov.au, phone +61 2 6221 6881 or fax +61 2 6232 8426

Australian Government

Department of Health

Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2016-CE-01982-1

Issued to:

Musculoskeletal Transplant Foundation

Manufacturing Site Address:

1175 Mid Valley Drive
Olyphant 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 22 June 2017, 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 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: 22 June 2019

ISSUE DATE: 25 January 2018

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 8644 Fax: 02 6203 1605 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-2016-CE-01982-1

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)	Storage on site
Human Tissue	Allograft - Bone	Storage on site
Human Tissue	Musculoskeletal Tissue	Storage on site
Human Tissue	Not Applicable	Testing - Analytical/Biological

The following limitations are applicable to these manufacturing operations:

Testing is restricted to endotoxin testing by LAL assay.

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 8644 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

TGA Health Safety Regulation