Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Ms Katrina Carroll
Director Regulatory Affairs
Musculoskeletal Transplant Foundation
1175 Mid Valley Drive
Olyphant Pennsylvania 18447
United States of America

TGA Reference: 2014/019698

Subject: Issue of GMP certificate MI-2018-CE-11298-1

Dear Ms Carroll,

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

Jenny Hantzinikolas
Director, Inspections Section
Manufacturing Quality Branch

1 October 2024

Contact: GMP@health.gov.au, Phone: 1800 020 653

Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2018-CE-07229-1

Issued to:

Musculoskeletal Transplant Foundation

Manufacturing Site Address:

1232 Mid Valley Drive
Jessup Pennsylvania 18434-1823
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 to 24 May 2023, 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.

Issue Date: **1 October 2024** **Expiry Date:** **25 May 2025**

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: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au

Certificate of GMP Compliance of a Manufacturer

Certificate Number:

MI-2018-CE-07229-1

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	Musculoskeletal Tissue	Processing Storage on site Packaging and labelling Release for supply
	Allograft - Bone	
Testing Laboratory	Not applicable	Testing – Analytical
Testing Laboratory – Blood Tissue Cellular	Not applicable	Endotoxin Testing Microbiological Contamination Testing

The following limitations are applicable to these manufacturing operations:

Analytical testing is limited to residual calcium measurement of Human Tissues. Microbiological Contamination Testing is limited to environmental monitoring, water quality and in process bioburden testing of Human Tissues.

PO Box 100 Woden ACT 2606 ABN 40 939 406 804
Phone: 1800 020 653 Fax: 02 6203 1605 Email: info@tga.gov.au www.tga.gov.au