Australian Government
Department of Health
Therapeutic Goods Administration

Dr Rebeccah Brown
Vice President, Global Regulatory Affairs
MiMedx Group Inc
1775 West Oak Commons Court NE
MARIETTA GA 30062
UNITED STATES OF AMERICA

Our Reference: E17-1034

Dear Dr Brown,

**Subject: Issue of GMP certificate MI-2018-CE-11648-1**

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

Stephen Hart
Senior GMP Inspector
Manufacturing Quality Branch

9 November 2021

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-2018-CE-11648-1

**Issued to:**

MiMedx Group Inc

**Manufacturing Site Address:**

1775 West Oak Commons Court NE
MARIETTA GA 30062
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.

This certificate is issued based on a remote inspection of GMP compliance during COVID19 travel restrictions. From the knowledge gained during inspection of this manufacturer, the latest of, that was conducted on 19 to 25 February 2021, 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: 25 February 2023**

**ISSUE DATE: 9 November 2021**

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-2018-CE-11648-1

## MANUFACTURING OPERATIONS

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

| Manufacturing Type | Sterility | Product Category | Manufacturing Step |
|---|---|---|---|
| Human Tissues | Manufactured Aseptically | Amnion | Processing<br>Packaging and labelling<br>Storage on site<br>Release for supply |
| Testing Laboratory | Not Applicable | Not Applicable | Testing chemical and physical |

The following limitations are applicable to these manufacturing operations:

Testing chemical and physical is restricted to Karl Fischer testing for residual moisture.

This certificate authorises the manufacture of sterile therapeutic goods only where the sterilisation process is carried out under contract by a third party.

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.

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TGA Health Safety Regulation