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America

CERTIFICATE

No. QS6 17 09 68207 039

Certificate Holder: MP Biomedicals Asia Pacific Pte Ltd
2 Pioneer Place
Singapore 627885
SINGAPORE

Certification Mark:

Scope of Certificate: Design, Production and Distribution of In-Vitro Diagnostic Devices for Infectious Diseases, Immunology, and Molecular Diagnostics; Distribution of Instruments & Software Supporting In-Vitro Diagnostics; Production of Antigens, Antibodies and Proteins

Standard(s): ISO 13485:2016

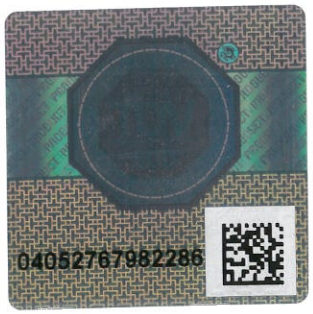
Regulatory Authority: TGA, ANVISA, Health Canada, FDA.
See attached for listing of specific regulatory requirements.

The Certification Body of TÜV SÜD America Inc. certifies that the quality management system of the manufacturer listed above has been audited against the stated criteria and found to conform to those criteria for the scope of certification listed. Validity of this certificate can be obtained by visiting the website
http://www.tuv-sud-america.com/us-en/resource-center/customer-support/certificate-finder

TÜV SÜD America Inc. is an MDSAP Authorized Auditing Organization.

DUNS No: 59-512-8042
Effective Date: 2017-09-29
Expiry Date: 2020-09-13

Manuel Bradaric
MHS Certification Manager



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America

CERTIFICATE

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Audit/Certification Criteria

Australia

- Therapeutic Goods (Medical Devices) Regulations 2002
- Schedule 3, Part 1
- Schedule 3, Part 4

Brazil

- Federal Law n. 6360/76
- RDC ANVISA n. 16/2013
- RDC ANVISA n. 23/2012
- RDC ANVISA n. 67/2009
- RDC ANVISA n. 56/2001

Canada

- Medical Device Regulations SOR/98-282, Part 1

United States

- 21 CFR Part 803
- 21 CFR Part 806
- 21 CFR Part 807
- 21 CFR Part 820
- 21 CFR Part 821

Effective Date: 2017-09-29
Expiry Date: 2020-09-13

Manuel Bradaric
Certification Manager MHS

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