



Certificate Number
MRA Q00005

Australian Government

Department of Health
Therapeutic Goods Administration

EC Certificate

Product Quality Assurance Procedures

Annex VI of the Council Directive 93/42/EEC on Medical Devices

Issued to:

Manufacturer Name: Medical Developments International Limited

Manufacturer Address: 4 Caribbean Drive
SCORESBY VICTORIA, 3179
Australia

For the Final inspection of device categories listed on page two of this certificate.

This is to certify that the quality management system described below conforms to the relevant provisions of Annex VI of the Council Directive 93/42/EEC on medical devices. Certification is based on an examination of the Quality Management System for final inspection to ensure each medical device to which the system is applied conforms to the product described in the Type Examination or the technical documentation as applicable.

Commencement Date: 20 October 2020

Certificate Expiry Date: 26 May 2024

Associated CA Certificate: AU Q00037

This certificate is issued by:

Jie ZHOU

Signed electronically

Delegate of the Secretary

Medical Devices Branch

Therapeutic Goods Administration

PO Box 100, Woden ACT 2606 Australia

**Notified Body
Identification number**

805



Australian Government
Department of Health
Therapeutic Goods Administration

Scope of Certificate

Manufacturer Facilities

Name and Address		Scope
1.	Medical Developments International Limited 4 Caribbean Drive SCORESBY VICTORIA, 3179 Australia	Administration, receipt of materials and products, dispatch of finished goods, packaging, warehousing, manufacturing, servicing operations, assembly and clean room.
2.	Medical Developments International Limited 56 Smith Road (Building 8) SPRINGVALE VICTORIA, 3171 Australia	Administration, receipt of materials and products, dispatch of finished goods, packaging, warehousing, manufacturing, assembly and clean room.

Final Inspection of Device Categories

Description		Limitations (if applicable)
1.	Peak flow spirometers	
2.	Carbon dioxide absorbers (single use and reusable)	
3.	Face masks	



Australian Government
Department of Health
Therapeutic Goods Administration

Certificate History

Version	Details	Issue Date	File Reference
1.1	Initial certification	17 August 1999	1999/040434
1.2	Change of manufacturer name from: <i>Medical Developments Australia Pty Ltd</i> to <i>Medical Developments International Limited</i> Added Breath Alert Peak Flow Meter to certificate which was previously on separate certificate - MM Q00006/01.	05 March 2004	1999/037092
2.1	Renewal of expired certificate, and changed flow meter GMDN code from: <i>GMDN 33151 Flowmeter, gas, pneumotachometer</i> to <i>GMDN 31300 Spirometer, peak flow</i>	23 August 2005	2005/010742
2.2	Extension of Validity of Certificate	17 February 2011	2010/004395
3.1	Recertification and change to format of certificate	23 June 2011	2010/004395
3.2	Addition of 'Manufacturer Facilities' details to scope of certificate	12 December 2014	2014/046187
3.3	Clarification of scope for Building 8	18 February 2015	2015/002001



Australian Government
Department of Health
Therapeutic Goods Administration

Version	Details	Issue Date	File Reference
4.1	<p>Recertification of certificate</p> <ul style="list-style-type: none">Change of manufacturer address: From: Factory 7, 56 Smith Road SPRINGVALE VIC 3171 AustraliaTo: 4 Caribbean Drive SCORESBY VICTORIA 3179 AustraliaRemoval of manufacturer facility details: 7/56 Smith Road (Buildings 5, 6, & 7) SPRINGVALE VIC 3171 AustraliaUpdate of manufacturer facility details including facility scope: 56 Smith Road (Building 8) SPRINGVALE VICTORIA 3171 AustraliaAddition of manufacturer facility details: 4 Caribbean Drive SCORESBY VICTORIA 3179 AustraliaAddition of device category: Face masks <p>Update to the certificate version numbers as internal TGA modifications</p>	22 June 2016	2015/021280 2015/030599
4.2	Confirmation of extension of scope activity to include packaging and clean room operations at the SCORESBY site.	12 September 2016	2016/007013
5.1	Re-issue of certificate up to 26 May 2024	20 October 2020	E19-694436
Certificate Location (Manufacturer Root File Number):			2010/010698