

Declaration of Conformity

PRODUCT IDENTIFICATION		
Product name	Model/number	
Silicone Face Mask – Small	CI-FM-SMALL-PIK	
Silicone Face Mask – Medium	CI-FM-MEDIUM-PIK	
Silicone Face Mask – Large	CI-FM-LARGE-PIK	
MANUFACTURER		
Name of company	Address	Representative
Medical Developments International Limited	4 Caribbean Drive, Scoresby, Victoria 3179 Australia	Neil Issa Head of Quality
AUTHORISED REPRESENTATIVE		
Name of company	Address	Contact details
Emergo Europe	Prinsessegracht 20 2514 AP The Hague The Netherlands	Ph: +31 70 345 8570
REGISTRATION INFORMATION		
Conformity assessment body	Certificate Number	
Department of Health, Therapeutic Goods Administration – ID 0805	MRA Q00005	
CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class IIa Annex IX (Classification Criteria) 1.2 Rule 2	Annex VI of MDD 93/42/EEC	ISO 13485:2016

Medical Developments International Limited declares that the above mentioned products meet the provision of the Council Directive 93/42/EEC for Medical Devices. All supporting documentation is retained at the premises of the manufacturer.

COMPANY REPRESENTATIVE: Keely So

SIGNATURE: 

TITLE: Senior Regulatory Affairs Associate

DATE: 31 January 2020