

Declaration of Conformity

PRODUCT IDENTIFICATION		
Product name	Model/number	
PiC Solution AirChamber (Antistatic Compact Space Chamber Plus)	SP-SPAP-ANTI-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
CONFORMITY ASSESSMENT		
Device classification	Route to compliance	Standards applied
Class I Annex IX, III 2.1, Rule 5 GMDN 38018	Annex VII 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