Declaration of Conformity

PRODUCT IDENTIFICATION		
Product name	**Model/number**	**Pikdare Code**
Combination Pack: PiC Solution AirChamber (Antistatic Compact Space Chamber Plus) & Small Mask PiC Solution AirChamber (Antistatic Compact Space Chamber Plus) & Medium Mask PiC Solution AirChamber (Antistatic Compact Space Chamber Plus) & Large Mask	 SP-ANTI-SS-PIK SP-ANTI-SM-PIK SP-ANTI-SL-PIK	 02010326000000 02010327000000 02010328000000

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**
N/A	Article 12 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; and has verified the mutual compatibility of the devices in accordance with the manufacturers' instructions; and has carried out his operations in accordance with the instructions; and has packaged the system or procedure pack and supplied the relevant information to users incorporating relevant instructions from the manufacturers; and the whole activity is subjected to appropriate methods of internal control and inspection.

All supporting documentation is retained at the premises of the manufacturer.

COMPANY REPRESENTATIVE: Keely So

SIGNATURE: _____

TITLE: Senior Regulatory Affairs Associate

DATE: 21 January 2020