EU DECLARATION OF CONFORMITY

R 0.7 2025-07

Name of Manufacturer: PRODOL MEDITEC LIMITED

1/F, 4/F, Block C, NO.18, 7th Science; Zhuhai; Guangdong 519085; China

SRN (Single Registration Number): CN-MF-000014746

EU Authorised Representative: PRODOL MEDITEC SA

Muelle Tomas Olavarri 5, 3º, 48930 Las Arenas, Spain

SRN (Single Registration Number): ES-AR-000005064

PRODUCTS INCLUDED:

Basic UDI-DI (GMN): 069360261A60023

Device Classification: Class I, non-sterile (according to EU 2017/745 MDR, Annex VIII).

Reference	Description	GMDN
A600	Airtraq Plus Video Laryngoscope & Included Spared Parts: A690, A691, A692, A680, A681, A620, A630	64798
A6C0	Airtraq Plus Video Laryngoscope Blade Channeled Infant Size 0	64797
A6C1	Airtraq Plus Video Laryngoscope Blade Channeled Pediatric Size 1	
A6C2	Airtraq Plus Video Laryngoscope Blade Channeled Small Size 2	
A6C3	Airtraq Plus Video Laryngoscope Blade Channeled Regular Size 3	
A6M1	Airtraq Plus Video Laryngoscope Mac Blade Size 1	
A6M2	Airtraq Plus Video Laryngoscope Mac Blade Size 2	
A6M3	Airtraq Plus Video Laryngoscope Mac Blade Size 3	
A6M4	Airtraq Plus Video Laryngoscope Mac Blade Size 4	
A6HA	Airtraq Plus Video Laryngoscope Hyperangulated Blade "H"	

PRODOL MEDITEC SA DECLARES UNDER ITS RESPONSIBILITY THAT THE PRODUCTS ABOVE MENTIONED CONFORM WITH THE REQUIREMENTS OF THE FOLLOWING LEGISLATION:

EU 2017/745	**EU Regulation – Medical Devices,** Risk Class I not sterilized Device
2014/35/EU	**EU Directive – Safety of electrical equipment ("Low-Voltage Directive") (LVD)**
2014/30/EU	**EU Directive – Electromagnetic Compatibility (EMC)**
2014/53/EU	**EU Directive - Radio Equipment**

AND THE FOLLOWING HARMONISED STANDARDS HAVE BEEN APPLIED:

EN 60601-1	EN 60601-1:2006 + /AC:2010 +/A1:2013 (IEC 60601-1:2005 + /A1:2012)
EN 60601-1-2	EN 60601-1-2:2015 (IEC 60601-1-2:2014)
EN 60601-1-6	EN 60601-1-6:2010 (IEC 60601-1-6 :2010)
EN 300 328	EN 301 489-1
EN 301 489-1	EN 301 489-1 V2.2.3
EN 301 489-17	EN 301 489-17 V3.2.4
EN 62304	EN 62304:2006/A1:2015 (IEC 62304:2006/A1:2015)
EN ISO 13485	EN ISO 13485:2016
EN ISO 14971	EN ISO 14971:2019/A11:2021
EN 62366-1	EN 62366-1:2015/A1:2020 (IEC 62366-1:2015/AMD1:2020)
EN ISO 10993-1	EN ISO 10993-1:2020 (ISO 10993-1:2018)
EN ISO 20417	EN ISO 20417:2021 (ISO 20417:2021)
EN 15223-1	EN ISO 15223-1:2021 (ISO 15223-1:2021)

Luis A. Ruiz-Ozaita, General Manager, PRODOL MEDITEC SA

Getxo, Bizkaia	**23 July 2025**	RUIZ RUIZ, LUIS ANTONIO (FIRMA) Firmado digitalmente por RUIZ RUIZ, LUIS ANTONIO (FIRMA) Fecha: 2025.07.23 09:22:07 +02'00'
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