



HEALTHCARE

Medical Devices (Pvt) Ltd.
Wazirabad Road - 51050, Ugoki, Sialkot - Pakistan.

MD-QA-22-113

Rev # 01

November 30, 2024

Declaration of Conformity

We Medical Devices (Pvt) Ltd declares, under our sole responsibility, that the LARYNGOSCOPE which consists of the following Models and Types are of Class Is, and meet all the applicable provisions set out in Directive 93/42/EEC according to Annex V.

Article Description	Trade Name	GIMA Ref #	MD Catalog #
Laryngoscope Blade (Single Use), F.O. Miller No. 0	Lunalite 'D'	57991	810-411-00S
Laryngoscope Blade (Single Use), F.O. Miller No. 1	Lunalite 'D'	57992	810-411-01S
Laryngoscope Blade (Single Use), F.O. Macintosh No. 1	Lunalite 'D'	57996	810-401-01S
Laryngoscope Blade (Single Use), F.O. Macintosh No. 2	Lunalite 'D'	57997	810-401-02S
Laryngoscope Blade (Single Use), F.O. Macintosh No. 3	Lunalite 'D'	57998	810-401-03S
Laryngoscope Blade (Single Use), F.O. Macintosh No. 4	Lunalite 'D'	57999	810-401-04S
Laryngoscope Blade (Single Use), F.O. Macintosh No. 5	Lunalite 'D'	58000	810-401-05S
LunaLED F.O. Laryngoscope Handle Small, V-2 "Ready to Use" with LED illumination,	Lunalite 'D'	58018	810-459-25S
LunaLED F.O. Laryngoscope Handle Medium, V-2 "Ready to Use" with LED illumination	Lunalite 'D'	58019	810-457-25S

Applied Standards: ISO 13485:2016, ISO 14971:2019, ISO 15223-1:2021, ISO 780:2015, ISO 10993-5:2009, ISO 10993-10:2010, ISO 7376:2020, ISO 14644-1:2015, ISO 10993-7:2008, ISO 11607-2:2019, ISO 11135:2014, CE 1639, IEC 60601-1:2005+A1:2012+A2:2020, IEC 60601-1-2:2014+AMD1:2020, IEC 62366-1:2015, IEC 60601-1-6, RoHS II Directive 2011/65/EU and RoHS III Directive 2015/863/EU

EC Certificate Number: **PK19/818842597.01**, Valid Till 24th May 2024.

ISO 13485:2016 Certificate Number: **PK04/61153.01**, Valid Till 20th April 2025.

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SIALKOT-PAKISTAN
Place (City & Country)

QUALITY ASSURANCE MANAGER
Position of Authorized person


Signature



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