

**Medical Devices (Pvt) Ltd.**

Wazirabad Road, Ugoki, Sialkot - Pakistan.

Declaration of Conformity

We **Medical Devices (PVT) LTD** hereby declares that the below mentioned devices have been classified according to the classification rules and conform to the Essential Principles for Safety and Performance as laid out in the Health products (Medical Devices) Regulations.

Manufacturer Site:**Medical Devices (PVT) LTD**

Wazirabad Road Ugoki

Sialkot. Pakistan.

Article Description	Gima Code	MD Cat. No
Speculum nasale Killian F.O. - 75mm	26777	K-7400
SET CANULE UTERINE (6 cannule + 1 manico)	28260	C-7585
TUBI ASPIRAZ.BIERER D.EST.8 mm	28262	B-7732
TUBI ESPIRAZ.BIERER D.EST.12mm (dispo sizes 10-14-16mm.)	28264	B-7728
Innesto portaluze angolato CLAMP	29975	A-7400
Manico Flyer LED	30794	
Manico Flyer	30795	F-7401
SET SPECCHI ORL - Clar mirror headlight		
Specchio LUX 100 - Ø 100mm -LED bulb- 3V mounted CR-123A	31107	808-706-30
Specchio LUX-55 - Ø 55mm - 6V mounted CR-123A battery box	31108	808-714-06
Specchio LUX-100 - Ø 100mm - 6V mounted CR-123A battery	31109	808-702-06
Spare head band (x tutti i codici)		808-791-01
Kit Specchio LUX-55 - Ø 55mm - 6V con borsa (31119)	31110	
Kit Specchio LUX-100-Ø 100mm-6V con borsa (31119)	31111	
Kit LUX-55 - Ø 55mm - 6V (kit completo)	31112	
Specchio per LUX-55	31114	808-781-55
Specchio di Clar per LUX-100	31115	808-780-10
Spare cable 30cm x cod 31108/9	31124	808-090-00
Dermatoscopio 10x in bors. Nylon + scat. Gima	31187	D-7840
Otoscopio Parker colour - verde	31435	O-7824
Otoscopio Parker colour - blu	31436	O-7822
Otoscopio Parker colour - giallo	31437	O-7825
Otoscopio Parker - a vite	31440	O-7803
Otoscopio - a baionetta	31440 B	O-7821
Otoscopio Parker - a baionetta con manico ricaricabile	31441	07-0002-0185-01
Set 3 speculum riutilizzabili	31448	X-7507
Diagnostic ENT vacuum light a baionetta	31471	D-7822
Diagnostic standard set-con oftalmo- a baionetta	31473	D-7802

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Manico fisso	31615	L-7854
Manico regolabile	31616	L-1001
LINEA UROLOGICA MD		
TESTA DI ILLUMINAZIONE	25953	819-100-01
ANOSCOPIO F.O. 15X70 MM.	29400	819-080-15
ANOSCOPIO F.O. 20X70 MM	29401	819-082-20
ANOSCOPIO F.O. 25X70 MM	29402	819-084-25
SET 3 ANOSCOPI F.O. IN SCATOLA	29403	X-7433
PROCTOSCOPIO F.O. 20X130 MM	29405	819-088-30
SIGMOIDOSCOPIO F.O. 12X200	29410	819-098-12
SIGMOIDOSCOPIO F.O. 16X250	29411	819-096-16
SIGMOIDOSCOPIO F.O. 21X200	29412	819-094-21
SIGMOIDOSCOPIO F.O. 21X250	29413	819-092-21
SIGMOIDOSCOPIO F.O. 21X300	29414	819-090-21
LENTE RICAMBIO SIGMOIDOSCOPIO		819-099-15
MANICO PER PINZE BIOPSIA	29420	819-600-00
PINZA BIOPSIA senza manico 3.5X8 mm. 420 mm- straight	29421	819-600-01
PINZA BIOPSIA senza manico 4 mm. 420 mm- straight	29422	819-610-01
SET LLOYD-DAVIS composto da:	29418	X-7453
PINZA PORTASPUGNA 400 MM	29425	819-610-40
TUBO ASPIRAZIONE 400 MM	29426	819-620-40
DOPPIA PERA PER INSUFFLAZIONE	29427	819-630-00
MANIPOLO PER CAVI F.O.	30798	B-7241 80801100
MANIPOLO ILLUMINATO 6V. ALOG.	30799	B-7240 80801300
SET LARINGO CONVENZIONALI -2,5V		
SET PED 2 LAME MILLER 0-1	34301	X-7365
SET ADULTI 3 LAME MC-INT 2-3-4	34302	810-831-02
SET ADULTI 4 LAME MC-INT 1-2-3-4	34303	810-831-03
SET PED. 3 LAME MILLER 0-1 + MC-INT 0	34305	X-7080
DOCTOR SET 3 LAME MILLER 1-2-3 (con manico adult/medium)	34306	810-841-01
SET PED 3 LAME MILLER 00-0-1	34307	810-841-02
LAME PER LARINGO STANDARD CONVENZIONALI		
LAME CONVEN. MILLER NR.00 OXY"	34310	M-7023
LAME CONVEN. MILLER NR.0	34311	810-211-00
LAME CONVEN. MILLER NR.1	34312	810-211-01
LAME CONVEN. MILLER NR.2	34313	810-211-02
LAME CONVEN. MILLER NR.3	34314	810-211-03

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ZOOM Charging Station, Input 220.0V EU Standard	31542	808-053-00
Reusable Ear Cannula Set of 5, Black with Metal Ring, Polish. -	31451	07-0006-0955-01

It is certified that the above-mentioned medical devices are, of **class 1** according to appendix IX are manufactured and finally inspected by us to meet the provisions of Council Directive 93/42/EEC with amendment of 2007/47/EC of 14 June 1993 Concerning Medical Devices.

Applied Standards

ISO 13485:2016, ISO 14971:2012, ISO 15223-1:2016(E), ISO 7376: 2009, ISO 10942:2006, ANSI/AAMI ES60601-1: A1:2012, C1:2009/(R)2012 and A2:2010/(R)2012, CSA CAN/CSA-C22.2 NO. 60601-1:14

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SIALKOT- PAKISTAN
Place (City & Country)

QA MANAGER
Position of Authorized Person


Signature

