

TECHNICAL SHEET

Flexible Video- Rhino-Laryngoscope RP11A

Manufacturer:	Zhongshan Wese Meditech Co., Ltd. 6F, Building C, No.2 Jianshuo Street, South China Modern Chinese Medicine Park, HoChung Village, Nanlang town, Zhongshan City, Guangdong Province, China, 528451
Sole distributor for Italy:	X-MED S.r.l. Via Statale Sud, 113 41037 Mirandola, (MO), IT
Model:	Multi-use Flexible Video- Rhino-Laryngoscope
Product code:	RP11A
Classification based on UE 2017/745 regulation:	Class I
Medical Device Register Identification Number (RDM):	2605186/R
CND Classification:	Z12021005 - NASO FARINGO/LARINGOSCOPI

Intended uses:

RP11A Video-Rhino-Laryngoscope is used for diagnostic tests on patients suffering from otorhinolaryngological conditions. The device is indicated for the display and the endoscopic diagnosis of the oral, nose cavity, and upper airways anatomy.

Description:

The device is used only with the endoscopic video processors C100A and M110A. Whilst in use, the cold light emitted from the distal end of the LED light source illuminates the observation area. CMOS image sensor receives the light reflected by the surface of the mucosa and transforms the optical signal into an electrical signal, and these are transmitted to the processor via the cable.

Technical characteristics:

Model	RP11A	
Input voltage	5V DC (Please use the endoscope video processor specified by the manufacturer).	
Operational length	External Diameter	2 mm
	Length	340 mm±10%
Optical system	View field	110°±15%
	View direction	0~4°, ±10°
	Focus length	150 mm
Foldable tip	Angle	Top 130°, Bottom 130°, maximum deviation - 10% (without maximum limit).
Use in normal conditions	Environmental temperature	5°C~+40°C
	Atmospheric pressure	700hPa 1060hPa
	Relative humidity	30%~ 85%
Transport and storage conditions	Environmental temperature	-10°C~+55°C
	Atmospheric pressure	500hPa~1060hPa
	Relative humidity	≤93%
CE Classification		Class I
Level of protection against electric shock		BF
Level of protection against explosion risk		Ordinary equipment, without protection against explosion risk
Level of protection against liquid inlet		Handle, IPX7
Type of instrument		Portable
Disinfection method		Method recommended by the manufacturer
Operation mode		Continuous operation
Device lifespan		1000 uses or 5 years

Material included in the package

RP11A device is packaged individually in a rigid case containing:

- Endoscope
- Cover cap for the connector of the connection cable
- Manual compressed air pump (Leakage tester)
- Printed user manual.