

DECLARATION OF CONFORMITY

Code	Description
A.4018LST	SELF-LED-LIGHT - Diagnostic/paediatric fluted beaked proctoscope. Disposable. Tube length 56mm. Tube diameter 18 mm. Sterile
A.4018ST	SELF-LIGHT - Diagnostic/paediatric fluted beaked proctoscope. Tube length 56mm. Tube diameter 18 mm. Disposable & Sterile
A.4019LST	SELF-LED-LIGHT - Diagnostic/paediatric trunk-end proctoscope. Disposable. Tube length 54mm. Tube diameter 18mm. Sterile
A.4019ST	SELF-LIGHT - Diagnostic/paediatric trunk-ended proctoscope. Tube length 54mm. Tube diameter 18 mm. Disposable & Sterile
A.4021.1LST	Self-LED-lighting "MIDI" BLUE SCOPE - Surgical/Examination trunk ended proctoscope. Disposable. Tube diameter 21mm. Disposable and sterile.
A.4021.1ST	Self-lighting "MIDI" BLUE SCOPE - Surgical/Examination trunk ended proctoscope. Disposable. Tube diameter 21mm. Disposable and sterile.
A.4021LST	Self-LED-lighting "MIDI" BLUE SCOPE - Surgical/Examination trunk ended proctoscope. Disposable. Tube diameter 21mm. Disposable and sterile.
A.4021ST	Self-lighting "MIDI" BLUE SCOPE - Surgical/Examination trunk ended proctoscope. Disposable. Tube diameter 21mm. Disposable and sterile.
A.4022.1LST	Self-LED-lighting BLUE SCOPE - Surgical/Examination trunk ended proctoscope. Disposable. Tube length 79mm. Tube diameter 21mm. Sterile
A.4022.1ST	BLU-SCOPE - Surgical/Examination trunk-end proctoscope. Tube length 79mm. Tube diameter 23mm. Disposable & Sterile
A.4022LST	Self-LED-lighting BLUE SCOPE - Surgical/Examination trunk ended proctoscope. Disposable. Tube length 79mm. Tube diameter 21mm. Sterile
A.4022ST	BLU-SCOPE - Surgical/Examination trunk-end proctoscope. Tube length 79mm. Tube diameter 23mm. Disposable & Sterile
A.4023.1LST	SELF-LED-LIGHT - Surgical/Examination fluted beaked proctoscope. Disposable. Tube length 88mm. Tube diameter 23mm. Sterile
A.4023.1ST	SELF-LIGHT - Surgical/Examination fluted beaked proctoscope. Disposable. Tube length 88mm. Tube diameter 23mm. Sterile
A.4023B	Kit made of Sapimed Self-Light anoscope ref. A.4023ST complete with introducer with working channel
A.4023LST	SELF-LED-LIGHT - Surgical/Examination fluted beaked proctoscope. Disposable. Self-retaining. Tube length 88mm. Tube diameter 23mm. Sterile
A.4023ST	SELF-LIGHT - Surgical/Examination fluted beaked proctoscope. Tube length 88mm. Tube diameter 23mm. Disposable & Sterile. Self-retaining
A.4024.1LST	SELF-LED-LIGHT - Surgical/Examination trunk-end proctoscope. Disposable. Tube length 65mm. Tube diameter 23mm. Sterile
A.4024.1ST	SELF-LIGHT - Surgical/Examination trunk-end proctoscope. Tube length 65mm. Tube diameter 23mm. Disposable & Sterile
A.4024LST	SELF-LED-LIGHT - Surgical/Examination trunk-end proctoscope. Disposable. Self-retaining. Tube length 65mm. Tube diameter 23mm. Sterile
A.4024ST	SELF-LIGHT - Surgical/Examination trunk-end proctoscope. Tube length 65mm. Tube diameter 23mm. Disposable & Sterile
A.4025ST	ARAMIS is a disposable surgical device for the transanal minimally invasive surgery of rectal pathologies
A.4026ST	Anoscope for H.R.A. (High Resolution Anoscopy) Ø mm. 24,5 Sterile & Disposable with built-in LED light
A.4051	COLO-SHOWER - Device to perform rectal irrigation anally complete with spike, clamp and collecting bag. Disposable & sterile.
A.4080.1	Disposable trunk-end anal retractor with eyelet. Sterile & disposable.
A.4080.1L	Disposable trunk-end anal retractor with eyelet and built-in LED light. Sterile & disposable.
A.4080.2	BUDDY cap with petals. Sterile & disposable.
A.4080.3	SPATOLA surgical spatula. Sterile & disposable.
A.4081LST	Disposable trunk-end anal retractor with built-in LED light. Sterile
A.4081ST	Trunk-end anal retractor with built-in LED light. Disposable & Sterile
A.4082	BASILE'S CONE RETRACTOR - Sterile anal retractor. Disposable. Self-lighting
A.4082L	BASILE'S CONE RETRACTOR - Sterile anal retractor and built-in LED light. Disposable. Self-lighting
A.4083	THE BEAK - Surgical proctoscope. Disposable & sterile. Transparent. Self-lighting.
A.4083L	THE BEAK - Surgical proctoscope with built-in LED light. Disposable & sterile. Transparent. Self-lighting.
A.4084	THE BEAK Diagnostic- Disposable proctoscope. Transparent. Sterile & Self-lighting.
A.4084L	THE BEAK Diagnostic- Disposable proctoscope with built-in LED light. Transparent. Sterile & Self-lighting.
A.4085	NIGRASPUD - Surgical retractor. Disposable & sterile.
A.4086	EPOFLIER - Surgical kit made of a 34,3mm wide anoscope and an opened retractor named GULL. Disposable & sterile.
A.4086.1	GULL - opened retractor. Disposable & sterile.
A.4087.1	ERODe EndoRectal Operative Device, made of 1 surgical anoscope, 1 Slider, and 1 knot-pusher. Disposable and sterile.
A.4087.1L	ERODe EndoRectal Operative Device, made of 1 surgical anoscope, 1 Slider, and 1 knot-pusher. Disposable and sterile with built-in LED light
A.4088	L-Bet88 closed anoscope with window complete with knot-pusher. Self-retaining, disposable and sterile.
A.4088L	L-Bet88 closed anoscope with window complete with knot-pusher. Self-retaining, disposable and sterile with built-in LED light.
A.4513	Sterile and disposable kit made of a 130mm long proctoscope and a grip.
A.4513I	Sterile and disposable kit made of a 130mm long proctoscope, a grip and an insufflator
A.4513IP	Rectoscopy 130 mm long complete with a grip, insufflator & a dispose bag. Disposable & sterile
A.4513L	Sterile and disposable kit made of a 130mm long proctoscope and a grip. Self-LED lighting.
A.4513LI	Sterile and disposable kit made of a 130mm long proctoscope, a grip and an insufflator. Self-LED lighting.
A.4519	MPR Short - Multi Purpose Rectoscopy. 190mm long. Sterile & Disposable
A.4519I	MPR Short - Multi Purpose Rectoscopy. 190mm long. Sterile & Disposable. With insufflator.
A.4519L	MPR Short - Multi Purpose Rectoscopy. 190mm long. Sterile & Disposable. Self-LED lighting.
A.4519LI	MPR Short - Multi Purpose Rectoscopy. 190mm long. Sterile & Disposable. With insufflator. Self-LED lighting.
A.4520	Sterile and disposable kit made of a 200mm long rectoscopy and a grip.
A.4520I	Sterile and disposable kit made of a 200mm long rectoscopy, a grip and an insufflator
A.4520IP	Rectoscopy 200 mm long complete with a grip, insufflator & a dispose bag. Disposable & sterile
A.4520L	Sterile and disposable kit made of a 200mm long rectoscopy and a grip. Self-LED lighting.
A.4520LI	Sterile and disposable kit made of a 200mm long rectoscopy, a grip and an insufflator. Self-LED lighting.
A.4522	MPR - Multi Purpose Rectoscopy. 220mm long. Sterile & Disposable
A.4522I	MPR - Multi Purpose Rectoscopy. 220mm long. Sterile & Disposable. With insufflator.
A.4522L	MPR - Multi Purpose Rectoscopy. 220mm long. Sterile & Disposable. Self-LED lighting.
A.4522LI	MPR - Multi Purpose Rectoscopy. 220mm long. Sterile & Disposable. With insufflator. Self-LED lighting.
A.4525	Tube 250mm long complete with grip. Disposable and sterile
A.4525I	Tube 250mm long complete with grip and insufflator. Disposable and sterile
A.4525IP	Rectoscopy 250 mm long complete with a grip, insufflator & a dispose bag. Disposable & sterile
A.4525L	Tube 250mm long complete with grip. Disposable and sterile. Self-LED lighting.

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Code	Description
A.4525LI	Tube 250mm long complete with grip and insufflator. Disposable and sterile. Self-LED lighting.
A.4525V	Green tube 250mm long complete with grip. Disposable and sterile
A.4525VI	Green tube 250mm long complete with grip and insufflator. Disposable and sterile
A.4525VL	Green tube 250mm long complete with grip. Disposable and sterile. Self-LED lighting.
A.4525VLI	Green tube 250mm long complete with grip and insufflator. Disposable and sterile. Self-LED lighting.
A.5001	Quadrijet - for periana anaesthesia
A.5015	SCLEROJET - Device for haemorrhoid sclerotherapy. Disposable & Sterile.
A.8200ST	Insufflator in PVC - Disposable & Sterile
A.9023	SELFIST Dental blade mm. 23 for Park's retractor with push fasten. Sterile & disposable
A.9045	SELFIST Dental blade mm. 45 for Park's retractor with push fasten. Sterile & disposable
A.9060	SELFIST Dental blade mm. 60 for Park's retractor with push fasten. Sterile & disposable
A.9080	SELFIST Dental blade mm. 80 for Park's retractor with push fasten. Sterile & disposable
A.5015	SCLEROJET - Device for haemorrhoid sclerotherapy. Disposable & Sterile.
A.8200ST	Insufflator in PVC - Disposable & Sterile
A.9023	SELFIST Dental blade mm. 23 for Park's retractor with push fasten. Sterile & disposable
A.9045	SELFIST Dental blade mm. 45 for Park's retractor with push fasten. Sterile & disposable
A.9060	SELFIST Dental blade mm. 60 for Park's retractor with push fasten. Sterile & disposable
A.9080	SELFIST Dental blade mm. 80 for Park's retractor with push fasten. Sterile & disposable

Classification Annex IX MDD: class I Sterile

Sapimed S.p.A. declares the above mentioned medical devices are conforming to the Essential Requirements of Annex 1 and they're realized according to the requirements of the Amending Directive 93/42/EEC and subsequently modified by directive 2007/47, transposed in Italy with D.lgs. N° 37/2010. Technical Files and supporting documentation are retained under the premises of the Manufacturer at disposition of the Competent Authorities and Notified Body. Sapimed S.p.A. has developed a procedure for the vigilance system of the medical devices according to MEDDEV 2.12/1.

Harmonized European applicable rules:

The list of applicable rules is reported in the Technical Files.

Notified Body: IMQ S.p.A., Via Quintiliano 43, 20138 Milano, Italy
 Notified Body Nr: 0051

Certificate Nr.	Date of the Certificate	Expiry date
2101/MDD	22-02-2021	26-05-2024

SAPI MED spa
 Paola Oddenino