

## DICHIARAZIONE DI CONFORMITA' UE UE DECLARATION OF CONFORMITY

Fabbricante <i>Manufacturer</i>	SAPI MED Spa
Indirizzo <i>Address</i>	Via della Chimica, 6 Zona Industriale D3 15121 Alessandria (Italia)
Numero registrazione fabbricante (Banca Dati Eudamed) <i>Manufacturer registration number (Eudamed Data Base)</i>	<b>IT-MF-000023733</b>
Dispositivo Medico <i>Medical Device</i>	Vedi lista sotto See list below
Classificazione secondo All. VIII Regolamento UE 2017/745 <i>Classification according to UE Regulation 2017/745 Ann. VIII</i>	Classe I – (Regola 5) <i>Class I (Rule 5)</i>
Percorso di certificazione <i>Certification route</i>	Allegato IX, escluso Capo II <i>Annex IX, Chapter II excluded</i>

REF	Elenco codici vendita <i>List of codes for sale</i>	<i>Basic UDI-DI</i>
A.1001	DILATAN PLUS cryothermal anal dilator. Box of two different sizes 18/20 mm	803363880DLTORD6
A.1002	DILATAN PLUS cryothermal anal dilator. Box of two different sizes 23/27 mm	803363880DLTORD6
A.1003	DILATAN cryothermal anal dilator. Box of three different sizes.	803363880DLTORD6
A.1004	DILAGENT - anal dilator for treatment of fissures, haemorrhoids, hypertonia and postoperative stenosis	803363880DLTORD6
A.1030	DILATAN PLUS cryothermal anal dilator. Box of size 30 mm	803363880DLTORD6
A.1020	DILATAN cryothermal anal dilator size 20 mm	803363880DLTORD6
A.1023	DILATAN cryothermal anal dilator size 23 mm	803363880DLTORD6
A.1027	DILATAN cryothermal anal dilator size 27 mm	803363880DLTORD6
A.1020PLUS	DILATAN PLUS cryothermal anal dilator size 20 mm	803363880DLTORD6
A.1023PLUS	DILATAN PLUS cryothermal anal dilator size 23 mm	803363880DLTORD6
A.1027PLUS	DILATAN PLUS cryothermal anal dilator size 27 mm	803363880DLTORD6
A.2002	DILASTOM stomal dilator. Box of two different sizes.	803363880DLTORD6
A.4001	Disposable connector with operative windows for video camera and Sapimed Self-Light anoscope	803363880CNNTRCS
A.4002	Disposable connector for video camera and Sapimed grip ref A.4131	803363880CNNTRCS
A.4018	SELF-LIGHT - Diagnostic/paediatric flute beaked proctoscope. Disposable. Tube length 56mm. Tube diameter 18 mm (every 75 pcs. 1 pen-light free)	803363880ANSCPB6
A.4018L	SELF-LED-LIGHT - Diagnostic/paediatric flute beaked proctoscope. Disposable. Tube length 56mm. Tube diameter 18 mm	803363880ANSCPB6
A.4019	SELF-LIGHT - Diagnostic/paediatric trunk-end proctoscope. Disposable. Tube length 54mm. Tube diameter 18mm (every 75 pcs. 1 pen-light free)	803363880ANSCPB6
A.4019.1	SELF-LIGHT - Diagnostic/paediatric trunk-end proctoscope (with light shield). Disposable. Tube length 54mm. Tube diameter 18mm (every 75 pcs. 1 pen-light free)	803363880ANSCPB6
A.4019.1L	SELF-LED-LIGHT - Diagnostic/paediatric trunk-end proctoscope (with light shield). Disposable. Tube length 54mm. Tube diameter 18mm	803363880ANSCPB6
A.4019L	SELF-LED-LIGHT - Diagnostic/paediatric trunk-end proctoscope. Disposable. Tube length 54mm. Tube diameter 18mm	803363880ANSCPB6
A.4021	Self-lighting "MIDI" BLUE SCOPE - Surgical/Examination trunk ended proctoscope. Disposable. Tube diameter 21mm (every 50 pcs. 1 pen-light free)	803363880ANSCPB6
A.4021L	Self-LED-lighting "MIDI" BLUE SCOPE - Surgical/Examination trunk ended proctoscope. Disposable. Tube diameter 21mm	803363880ANSCPB6
A.4022	Self-lighting BLUE SCOPE - Surgical/Examination trunk ended proctoscope. Disposable. Tube length 79mm. Tube diameter 23mm (every 50 pcs. 1 pen-light free)	803363880ANSCPB6
A.4022L	Self-LED-lighting BLUE SCOPE - Surgical/Examination trunk ended proctoscope. Disposable. Tube length 79mm. Tube diameter 21mm	803363880ANSCPB6

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A.4023	SELF-LIGHT - Surgical/Examination flute beaked proctoscope. Disposable. Self-retaining. Tube length 88mm. Tube diameter 23mm (every 50 pcs. 1 pen-light free)	803363880ANSCPB6
A.4023.1	SELF-LIGHT - Surgical/Examination flute beaked proctoscope. Disposable. Tube length	803363880ANSCPB6
A.4023.1L	SELF-LED-LIGHT - Surgical/Examination flute beaked proctoscope. Disposable. Tube length 88mm. Tube diameter 23mm	803363880ANSCPB6
A.4023L	SELF-LED-LIGHT - Surgical/Examination flute beaked proctoscope. Disposable. Self-retaining. Tube length 88mm. Tube diameter 23mm	803363880ANSCPB6
A.4024	SELF-LIGHT - Surgical/Examination trunk-end proctoscope. Disposable. Self-retaining. Tube length 65mm. Tube diameter 23mm (every 50 pcs. 1 pen-light free)	803363880ANSCPB6
A.4024.1	SELF-LIGHT - Surgical/Examination trunk-end proctoscope. Disposable. Tube length 65mm. Tube diameter 23mm (every 50 pcs. 1 pen-light free)	803363880ANSCPB6
A.4024.1L	SELF-LED-LIGHT - Surgical/Examination trunk-end proctoscope. Disposable. Tube length 65mm. Tube diameter 23mm	803363880ANSCPB6
A.4024L	SELF-LIGHT - Surgical/Examination trunk-end proctoscope. Disposable. Self-retaining. Tube length 65mm. Tube diameter 23mm (every 50 pcs. 1 pen-light free)	803363880ANSCPB6
A.4026	Anoscope for H.R.A. (High Resolution Anoscopy) Ø mm. 23. Disposable. (every 50 pcs. 1 pen-light free)	803363880ANSCPB6
A.4026L	Self-LED-light anoscope for H.R.A. (High Resolution Anoscopy) Ø mm. 23. Disposable. (every 50 pcs. 1 pen-light free)	803363880ANSCPB6
A.4030	MFA Multi-Functional Anoscope. Ø mm. 23. Disposable.	803363880ANSCPB6
A.4081	Disposable trunk-end anal retractor (every 25 pcs. 1 pen-light free)	803363880ANSCPB6
A.4081L	Disposable trunk-end anal retractor (every 25 pcs. 1 pen-light free) with built-in LED light	803363880ANSCPB6
A.4084LNS	THE BEAK Diagnostic - Disposable proctoscope with built-in LED light. Transparent. Self-lighting.	803363880ANSCPB6
A.4084NS	THE BEAK Diagnostic - Disposable proctoscope. Transparent. Self-lighting.	803363880ANSCPB6
A.4100	Kit Rectosigmascope "Rigid-flexible" made up of 50x scopes + 3x re-usable grips	803363880RCTSCFF
A.4113	Disposable short rectoscope mm. 130 long. External diam. 21mm	803363880RCTSCFF
A.4120	Disposable paediatric rectoscope mm. 200 long. External diam. 15,1mm	803363880RCTSCFF
A.4125	Disposable rectoscope mm. 250 long. External diam. 21mm	803363880RCTSCFF
A.4125V	Disposable green colour rectoscope mm. 250 long. External diam. 21mm	803363880RCTSCFF
A.4130	Disposable Rectosigmascope "Rigid-flexible" mm. 300 long. External diam. 21mm	803363880RCTSCFF
A.4131	Grip for SAPI MED range of rectoscopes	803363880RCTSCFF
A.4131.1	Grip for SAPI MED range of rectoscopes with not magnifying lens	803363880RCTSCFF
A.4200	Kit rectoscope made up of 25x scopes + 2x re-usable grips	803363880RCTSCFF
A.4200V	Kit green colour rectoscope made up of 25x scopes + 2x re-usable grips	803363880RCTSCFF
A.4300	Kit short rectoscope made up of 25x scopes + 2x re-usable grips	803363880RCTSCFF
A.4400	Kit paediatric rectoscope made up of 25x scopes + 2x re-usable grips	803363880RCTSCFF
A.4513INS	Non sterile and disposable kit made of a 130mm long proctoscope, a grip and an insufflator	803363880RCTSCFF
A.4513LINS	Non sterile and disposable kit made of a 130mm long proctoscope, a grip and an insufflator. Self-LED lighting.	803363880RCTSCFF
A.4513LNS	Non sterile and disposable kit made of a 130mm long proctoscope and a grip. Self-LED lighting.	803363880RCTSCFF

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A.4513NS	Non sterile and disposable kit made of a 130mm long proctoscope and a grip.	803363880RCTSCFF
A.4519INS	MPR Short - Multi Purpose Rectoscope. 190mm long. Non-sterile & Disposable. With insufflator. Self-LED lighting.	803363880RCTSCFF
A.4519LINS	MPR Short - Multi Purpose Rectoscope. 190mm long. Non-sterile & Disposable. With insufflator. Self-LED lighting.	803363880RCTSCFF
A.4519LNS	MPR Short - Multi Purpose Rectoscope. 190mm long. Non-sterile & Disposable. Self-LED lighting.	803363880RCTSCFF
A.4519NS	MPR Short - Multi Porose Rectoscope. 190mm long. Non-sterile & Disposable	803363880RCTSCFF
A.4520INS	Non sterile and disposable kit made of a 200mm long rectoscope, grip and insufflator	803363880RCTSCFF
A.4520LINS	Non sterile and disposable kit made of a 200mm long rectoscope, a grip and an insufflator. Self-LED lighting.	803363880RCTSCFF
A.4520LNS	Non sterile and disposable kit made of a 200mm long rectoscope and a grip. Self-LED lighting.	803363880RCTSCFF
A.4520NS	Non sterile and disposable kit made of a 200mm long rectoscope and a grip.	803363880RCTSCFF
A.4522INS	MPR - Multi Purpose Rectoscope. 220mm long. Non sterile & Disposable. With insufflator. Self-LED lighting.	803363880RCTSCFF
A.4522LINS	MPR - Multi Purpose Rectoscope. 220mm long. Non sterile & Disposable. With insufflator. Self-LED lighting.	803363880RCTSCFF
A.4522LNS	MPR - Multi Purpose Rectoscope. 220mm long. Non sterile. Disposable. Self-LED lighting.	803363880RCTSCFF
A.4522NS	MPR - Multi Purpose Rectoscope. 220mm long. Non-sterile & Disposable.	803363880RCTSCFF
A.4525INS	Tube 250mm long complete with grip and insufflator. Disposable.	803363880RCTSCFF
A.4525LINS	Tube 250mm long complete with grip and insufflator. Disposable. Self-LED lighting.	803363880RCTSCFF
A.4525LNS	Tube 250mm long complete with grip. Disposable. Self-LED lighting.	803363880RCTSCFF
A.4525NS	Tube 250mm long complete with grip. Disposable.	803363880RCTSCFF
A.4525VINS	Green tube 250mm long complete with grip and insufflator. Disposable	803363880RCTSCFF
A.4525VLINS	Green tube 250mm long complete with grip and insufflator. Disposable. Self-LED lighting.	803363880RCTSCFF
A.4525VLNS	Green tube 250mm long complete with grip. Disposable. Self-LED lighting.	803363880RCTSCFF
A.4525VNS	Green tube 250mm long complete with grip. Disposable.	803363880RCTSCFF
A.5660	LEM - Disposable haemorrhoid banding ligator for use with forceps	803363880BNDLGTRKG
A.5660.3	LEM - Disposable haemorrhoid banding ligator for use with forceps complete with 3 rings	803363880BNDLGTRKG
A.5660.3LF	LEM - Disposable haemorrhoid banding ligator for use with forceps complete with 3 latex free rings	803363880BNDLGTRKG
A.5660.5	LEM - Disposable haemorrhoid banding ligator for use with forceps complete with 5 rings	803363880BNDLGTRKG
A.5660.5LF	LEM - Disposable haemorrhoid banding ligator for use with forceps complete with 5 latex free rings	803363880BNDLGTRKG
A.5661	LEM - Disposable haemorrhoid banding ligator for use with forceps complete with ring loader	803363880BNDLGTRKG
A.5661.3	LEM - Disposable haemorrhoid banding ligator for use with forceps complete with ring loader and 3 rings complete with rings loader and 3 rings	803363880BNDLGTRKG
A.5661.3LF	LEM - Disposable haemorrhoid banding ligator for use with forceps complete with ring loader and 3 latex free rings complete with rings loader and 3 latex	803363880BNDLGTRKG
A.5661.5	LEM - Disposable haemorrhoid banding ligator for use with forceps complete with rings loader and 5 rings	803363880BNDLGTRKG

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A.5661.5LF	LEM - Disposable haemorrhoid banding ligator for use with forceps complete with rings loader and 5 latex free rings	803363880BNDLGTRKG
A.8200	Disposable insufflator in PVC	803363880INSFFLG2
B.0300	ECOLITE - LED light source	803363880CLDLGHTJ7
B.0300UK	ECOLITE - LED light source modified for UK market	803363880CLDLGHTJ7
B.0306	Pen-LED-light for Sapi Med anoscopies, rectoscopes and retractors	803363880CLDLGHTJ7
B.0308	PEN-LIGHT pen for SELF-LIGHT proctoscopes	803363880CLDLGHTJ7
B.0310	Flash-Light - Portable light-source powered by rechargeable battery	803363880CLDLGHTJ7
B.0350	GLF 100 col light source	803363880CLDLGHTJ7
B.0351	180 cm optic fibres cable. Compatible with the whole range of SELF-LIGHT proctoscopes and rectoscopes	803363880CLDLGHTJ7
B.0354	AUTOCLAVABLE medical silicone 180 cm optic fibres cable. Compatible with the whole range of SELF-LIGHT proctoscopes and rectoscopes	803363880CLDLGHTJ7
B.0356	Spare Bulb for GLF 100	803363880CLDLGHTJ7
B.0362	180 cm optic fibres cable with special fitting to others Cold Light Sources	803363880CLDLGHTJ7
B.0364	AUTOCLAVABLE medical silicone 180 cm optic fibres cable with special fitting to others Cold Light Sources	803363880CLDLGHTJ7
B.0365	Autoclavable Teflon cable-end to connect with Wolf/Storz cables and to fit with Self-Light and Sapimed grips	803363880CLDLGHTJ7
B.0366	Black cable-end to connect with Wolf/Storz cables and to fit with Self-light and Sapimed grips	803363880CLDLGHTJ7
B.0500	FISIANAL - Audio anorectal biofeedback for home training of perianal hind muscles.	803363880PLVRHABWY

Il Fabbricante Legale "Sapi Med Spa" dichiara, sotto la propria esclusiva responsabilità, che il Dispositivo Medico sopra menzionato è conforme ai Requisiti Generali di Sicurezza e Prestazione del Regolamento UE 2017/745, di cui l'Allegato I e alle norme di prodotto e processo e applicabili. La Documentazione Tecnica contenente la documentazione pertinente è conservata presso il Fabbricante e messa a disposizione delle Autorità Competenti. Il Fabbricante Legale "Sapi Med Spa" ha sviluppato una procedura per la sorveglianza post vendita in accordo ai requisiti del Regolamento UE 2017/745 ed è il solo responsabile della presente Dichiarazione di Conformità UE.

The Legal Manufacturer "Sapi Med Spa" declares, under his own responsibility, that the above mentioned medical device is conforming to the General Safety and Performance Requirements of UE Regulation 2017/745 reported in Annex I and conforming to the applicable rules of product and process. Technical Documentation and supporting documentation are retained under the premises of the Manufacturer at disposition of the Competent Authorities. The Legal Manufacturer "Sapi Med Spa" has developed an internal procedure for the vigilance system of the medical devices according to the requirements of UE Regulation 2017/745 and is the only responsible for this EU Declaration of Conformity.

### Regolamenti e leggi applicabili *Applicable Regulations and Laws*

L'elenco degli standard applicabili è riportato nel Capitolo 4 della relativa Documentazione Tecnica.  
*List of applicable standards is reported in Chapter 4 of relative Technical Documentation.*

Alessandria, 26/05/2022

Paola Oddenino  
President / PRRC

