

## DICHIARAZIONE DI CONFORMITÀ UE

### EU- DECLARATION OF CONFORMITY

La Società **MEDI LINE S.R.L.** (SRN: IT-MF-000019935),  
 con sede legale in Via Trapezzoli, 44 89134 San Gregorio (RC) - Italia,  
 in qualità di fabbricante dei dispositivi medici:  
*The company **MEDI LINE S.R.L.** (SRN: IT-MF-000019935),  
 with registered office in Via Trapezzoli, 44 89134 San Gregorio (RC) - Italy,  
 as manufactured of the medical devices:*

CODICE DI VENDITA <i>Sales Code</i>	Nome commerciale / CARATTERISTICHE <i>Commercial name / FEATURES</i>	UDI-DI di base <i>Basic UDI- DI</i>
300-R3	X-ONE® Trocar dilatante 3mm cannula Corta <i>X-ONE® Bladeless trocar 3 mm Short cannula</i>	805511288K01010101LW
300-R5	X-ONE® Trocar dilatante 5mm cannula Standard <i>X-ONE® bladeless trocar 5 mm Standard cannula</i>	805511288K01010101LW
300-R5/3	X-ONE® Trocar dilatante 5/3mm cannula Standard <i>X-ONE® bladeless trocar 5/3 mm Standard cannula</i>	805511288K01010101LW
300-RS5	X-ONE® Trocar dilatante 5mm cannula Corta <i>X-ONE® bladeless trocar 5 mm Short cannula</i>	805511288K01010101LW
300-RS5/3	X-ONE® Trocar dilatante 5/3mm cannula Corta <i>X-ONE® bladeless trocar 5/3 mm Short cannula</i>	805511288K01010101LW
300-RL5	X-ONE® Trocar dilatante 5mm cannula Lunga <i>X-ONE® bladeless trocar 5 mm Long cannula</i>	805511288K01010101LW
300-RL5/3	X-ONE® Trocar dilatante 5/3mm cannula Lunga <i>X-ONE® bladeless trocar 5/3 mm Long cannula</i>	805511288K01010101LW
300-R8	X-ONE® Trocar dilatante 8mm cannula Standard <i>X-ONE® bladeless trocar 8 mm Standard cannula</i>	805511288K01010101LW
300-R11	X-ONE® Trocar dilatante 11mm cannula Standard <i>X-ONE® bladeless trocar 11 mm Standard cannula</i>	805511288K01010101LW
300-R12	X-ONE® Trocar dilatante 12mm cannula Standard <i>X-ONE® bladeless trocar 12 mm Standard cannula</i>	805511288K01010101LW
300-RS12	X-ONE® Trocar dilatante 12mm cannula Corta <i>X-ONE® bladeless trocar 12 mm Short cannula</i>	805511288K01010101LW
300-RL12	X-ONE® Trocar dilatante 12mm cannula Lunga <i>X-ONE® bladeless trocar 12mm Long cannula</i>	805511288K01010101LW
300-R15	X-ONE® Trocar dilatante 15mm cannula Standard <i>X-ONE® bladeless trocar 15 mm Standard cannula</i>	805511288K01010101LW
300-RL15	X-ONE® Trocar dilatante 15mm cannula Lunga <i>X-ONE® bladeless trocar 15mm Long cannula</i>	805511288K01010101LW
301-R5	X-ONE® Kit Trocar dilatante 5mm - 2 cannule Standard <i>X-ONE® Kit bladeless trocar 5 mm – 2 Standard cannulas</i>	805511288K01010101LW
301-R5/3	X-ONE® Kit Trocar dilatante 5/3mm - 2 cannule Standard <i>X-ONE® Kit bladeless trocar 5/3 mm – 2 Standard cannulas</i>	805511288K01010101LW
301-RS5	X-ONE® Kit Trocar dilatante 5mm - 2 cannule Corte <i>X-ONE® Kit bladeless trocar 5 mm – 2 Short cannulas</i>	805511288K01010101LW
301-RS5/3	X-ONE® Kit Trocar dilatante 5/3mm - 2 cannule Corte <i>X-ONE® Kit bladeless trocar 5/3 mm – 2 Short cannulas</i>	805511288K01010101LW
301-RL5	X-ONE® Kit Trocar dilatante 5mm - 2 cannule Lunghe <i>X-ONE® Kit bladeless trocar 5 mm – 2 Long cannulas</i>	805511288K01010101LW
301-RL5/3	X-ONE® Kit Trocar dilatante 5/3mm - 2 cannule Lunghe <i>X-ONE® Kit bladeless trocar 5/3 mm – 2 Long cannulas</i>	805511288K01010101LW
301-R8	X-ONE® Kit Trocar dilatante 8 mm - 2 cannule Standard <i>X-ONE® Kit bladeless trocar 8 mm – 2 Standard cannulas</i>	805511288K01010101LW



CODICE DI VENDITA Sales Code	Nome commerciale / CARATTERISTICHE Commercial name / FEATURES	UDI-DI di base Basic UDI- DI
301-R11	X-ONE® Kit Trocar dilatante 11mm - 2 cannule Standard <i>X-ONE® Kit bladeless trocar 11 mm – 2 Standard cannulas</i>	805511288K01010101LW
301-R12	X-ONE® Kit Trocar dilatante 12mm - 2 cannule Standard <i>X-ONE® Kit bladeless trocar 12 mm – 2 Standard cannulas</i>	805511288K01010101LW
301-RS12	X-ONE® Kit Trocar dilatante 12mm - 2 cannule Corte <i>X-ONE® Kit bladeless trocar 12 mm – 2 Short cannulas</i>	805511288K01010101LW
301-RL12	X-ONE® Kit Trocar dilatante 12mm - 2 cannule Lunghe <i>X-ONE® Kit bladeless trocar 12 mm – 2 Long cannulas</i>	805511288K01010101LW
301-R15	X-ONE® Kit Trocar dilatante 15mm - 2 cannule Standard <i>X-ONE® Kit bladeless trocar 15 mm – 2 Standard cannulas</i>	805511288K01010101LW
300-F5	X-ONE® Trocar a lama piatta 5mm cannula Standard <i>X-ONE® Flat blade Trocar 5 mm Standard cannula</i>	805511288K01010101LW
300-F5/3	X-ONE® Trocar a lama piatta 5/3mm cannula Standard <i>X-ONE® Flat blade Trocar 5/3 mm Standard cannula</i>	805511288K01010101LW
300-FS5	X-ONE® Trocar a lama piatta 5mm cannula Corta <i>X-ONE® Flat blade Trocar 5 mm Short cannula</i>	805511288K01010101LW
300-FS5/3	X-ONE® Trocar a lama piatta 5/3mm cannula Corta <i>X-ONE® Flat blade Trocar 5/3 mm Short cannula</i>	805511288K01010101LW
300-FL5	X-ONE® Trocar a lama piatta 5/3mm cannula Lunga <i>X-ONE® Flat blade Trocar 5/3 mm Long cannula</i>	805511288K01010101LW
300-FL5/3	X-ONE® Trocar a lama piatta 5mm cannula Lunga <i>X-ONE® Flat blade Trocar 5 mm Long cannula</i>	805511288K01010101LW
300-F11	X-ONE® Trocar a lama piatta 11mm cannula Standard <i>X-ONE® Flat blade Trocar 11 mm Standard cannula</i>	805511288K01010101LW
300-F12	X-ONE® Trocar a lama piatta 12mm cannula Standard <i>X-ONE® Flat blade Trocar 12 mm Standard cannula</i>	805511288K01010101LW
300-FL12	X-ONE® Trocar a lama piatta 12mm cannula Lunga <i>X-ONE® Flat blade Trocar 12 mm Long cannula</i>	805511288K01010101LW
300-F15	X-ONE® Trocar a lama piatta 15mm cannula Standard <i>X-ONE® Flat blade Trocar 15 mm Standard cannula</i>	805511288K01010101LW
301-F5	X-ONE® Kit Trocar a lama piatta 5mm - 2 cannule Standard <i>X-ONE® Kit Flat blade trocar 5 mm – 2 Standard cannulas</i>	805511288K01010101LW
301-F5/3	X-ONE® Kit Trocar a lama piatta 5/3mm - 2 cannule Standard <i>X-ONE® Kit Flat blade trocar 5/3 mm – 2 Standard cannulas</i>	805511288K01010101LW
301-FS5	X-ONE® Kit Trocar a lama piatta 5mm - 2 cannule Corte <i>X-ONE® Kit Flat blade trocar 5 mm – 2 Short cannulas</i>	805511288K01010101LW
301-FS5/3	X-ONE® Kit Trocar a lama piatta 5/3mm - 2 cannule Corte <i>X-ONE® Kit Flat blade trocar 5/3 mm – 2 Short cannulas</i>	805511288K01010101LW
301-FL5	X-ONE® Kit Trocar a lama piatta 5mm - 2 cannule Lunghe <i>X-ONE® Kit Flat blade trocar 5 mm – 2 Long cannulas</i>	805511288K01010101LW
301-FL5/3	X-ONE® Kit Trocar a lama piatta 5/3mm - 2 cannule Lunghe <i>X-ONE® Kit Flat blade trocar 5/3 mm – 2 Long cannulas</i>	805511288K01010101LW
301-F11	X-ONE® Kit Trocar a lama piatta 11mm - 2 cannule Standard <i>X-ONE® Kit Flat blade trocar 11 mm – 2 Standard cannulas</i>	805511288K01010101LW
301-F12	X-ONE® Kit Trocar a lama piatta 12mm - 2 cannule Standard <i>X-ONE® Kit Flat blade trocar 12 mm – 2 Standard cannulas</i>	805511288K01010101LW
301-FL12	X-ONE® Kit Trocar a lama piatta 12mm - 2 cannule Lunghe <i>X-ONE® Kit Flat blade trocar 12 mm – 2 Long cannulas</i>	805511288K01010101LW
301-F15	X-ONE® Kit Trocar a lama piatta 15mm - 2 cannule Standard <i>X-ONE® Kit Flat blade trocar 15 mm – 2 Standard cannulas</i>	805511288K01010101LW
300-V3	X-ONE® Trocar Ottico 3mm cannula Corta <i>X-ONE® Optical Trocar 3mm Short cannula</i>	805511288K01010103M2
300-V5	X-ONE® Trocar Ottico 5mm cannula Standard <i>X-ONE® Optical Trocar 5mm Standard cannula</i>	805511288K01010103M2



CODICE DI VENDITA <i>Sales Code</i>	Nome commerciale / CARATTERISTICHE <i>Commercial name / FEATURES</i>	UDI-DI di base <i>Basic UDI- DI</i>
300-V5/3	X-ONE® Trocar Ottico 5/3mm cannula Standard <i>X-ONE® Optical Trocar 5/3mm Standard cannula</i>	805511288K01010103M2
300-VS5	X-ONE® Trocar Ottico 5mm cannula Corta <i>X-ONE® Optical Trocar 5mm Short cannula</i>	805511288K01010103M2
300-VS5/3	X-ONE® Trocar Ottico 5/3mm cannula Corta <i>X-ONE® Optical Trocar 5/3mm Short cannula</i>	805511288K01010103M2
300-VL5	X-ONE® Trocar Ottico 5mm cannula Lunga <i>X-ONE® Optical Trocar 5mm Long cannula</i>	805511288K01010103M2
300-VL5/3	X-ONE® Trocar Ottico 5/3mm cannula Lunga <i>X-ONE® Optical Trocar 5/3mm Long cannula</i>	805511288K01010103M2
300-V8	X-ONE® Trocar Ottico 8mm cannula Standard <i>X-ONE® Optical Trocar 8mm Standard cannula</i>	805511288K01010103M2
300-V11	X-ONE® Trocar Ottico 11mm cannula Standard <i>X-ONE® Optical Trocar 11mm Standard cannula</i>	805511288K01010103M2
300-V12	X-ONE® Trocar Ottico 12mm cannula Standard <i>X-ONE® Optical Trocar 12mm Standard cannula</i>	805511288K01010103M2
300-VS12	X-ONE® Trocar Ottico 12mm cannula Corta <i>X-ONE® Optical Trocar 12mm Short cannula</i>	805511288K01010103M2
300-VL12	X-ONE® Trocar Ottico 12mm cannula Lunga <i>X-ONE® Optical Trocar 12mm Long cannula</i>	805511288K01010103M2
300-V15	X-ONE® Trocar Ottico 15mm cannula Standard <i>X-ONE® Optical Trocar 15mm Standard cannula</i>	805511288K01010103M2
301-V3	X-ONE® Kit Trocar Ottico 3mm - 2 cannule Corte <i>X-ONE® Kit Optical trocar 3mm – 2 Short cannulas</i>	805511288K01010199N9
301-V5	X-ONE® Kit Trocar Ottico 5mm - 2 cannule Standard <i>X-ONE® Kit Optical trocar 5mm – 2 Standard cannulas</i>	805511288K01010199N9
301-V5/3	X-ONE® Kit Trocar Ottico 5/3mm - 2 cannule Standard <i>X-ONE® Kit Optical trocar 5/3mm – 2 Standard cannulas</i>	805511288K01010199N9
301-VS5	X-ONE® Kit Trocar Ottico 5mm - 2 cannule Corte <i>X-ONE® Kit Optical trocar 5mm – 2 Short cannulas</i>	805511288K01010199N9
301-VS5/3	X-ONE® Kit Trocar Ottico 5/3mm - 2 cannule Corte <i>X-ONE® Kit Optical trocar 5/3mm – 2 Short cannulas</i>	805511288K01010199N9
301-VL5	X-ONE® Kit Trocar Ottico 5mm - 2 cannule Lunghe <i>X-ONE® Kit Optical trocar 5mm – 2 Long cannulas</i>	805511288K01010199N9
301-VL5/3	X-ONE® Kit Trocar Ottico 5/3mm - 2 cannule Lunghe <i>X-ONE® Kit Optical trocar 5/3mm – 2 Long cannulas</i>	805511288K01010199N9
301-V8	X-ONE® Kit Trocar Ottico 8mm - 2 cannule Standard <i>X-ONE® Kit Optical trocar 8mm – 2 Standard cannulas</i>	805511288K01010199N9
301-V11	X-ONE® Kit Trocar Ottico 11mm - 2 cannule Standard <i>X-ONE® Kit Optical trocar 11mm – 2 Standard cannulas</i>	805511288K01010199N9
301-V12	X-ONE® Kit Trocar Ottico 12mm - 2 cannule Standard <i>X-ONE® Kit Optical trocar 12mm – 2 Standard cannulas</i>	805511288K01010199N9
301-VS12	X-ONE® Kit Trocar Ottico 12mm - 2 cannule Corte <i>X-ONE® Kit Optical trocar 12mm – 2 Short cannulas</i>	805511288K01010199N9
301-VL12	X-ONE® Kit Trocar Ottico 12mm - 2 cannule Lunghe <i>X-ONE® Kit Optical trocar 12mm – 2 Long cannulas</i>	805511288K01010199N9
301-V15	X-ONE® Kit Trocar Ottico 15mm - 2 cannule Standard <i>X-ONE® Kit Optical trocar 15mm – 2 Standard cannulas</i>	805511288K01010199N9
300-H11	X-ONE® Trocar di Hasson 11mm cannula Standard <i>X-ONE® Hasson Trocar 11mm Standard cannula</i>	805511288K01010102LY
300-H12	X-ONE® Trocar di Hasson 12mm cannula Standard <i>X-ONE® Hasson Trocar 12mm Standard cannula</i>	805511288K01010102LY
300-RF5	X-ONE® Trocar Hybrid 5mm cannula Standard <i>X-ONE® Hybrid Trocar 5mm Standard cannula</i>	805511288K01010101LW



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300-RF5/3	X-ONE <sup>®</sup> Trocar Hybrid 5/3mm cannula Standard <i>X-ONE<sup>®</sup> Hybrid Trocar 5/3mm Standard cannula</i>	805511288K01010101LW
300-RFS5	X-ONE <sup>®</sup> Trocar Hybrid 5mm cannula Corta <i>X-ONE<sup>®</sup> Hybrid Trocar 5mm Short cannula</i>	805511288K01010101LW
300-RFS5/3	X-ONE <sup>®</sup> Trocar Hybrid 5/3mm cannula Corta <i>X-ONE<sup>®</sup> Hybrid Trocar 5/3mm Short cannula</i>	805511288K01010101LW
300-RF11	X-ONE <sup>®</sup> Trocar Hybrid 11mm cannula Standard <i>X-ONE<sup>®</sup> Hybrid Trocar 11mm Standard cannula</i>	805511288K01010101LW
300-RF12	X-ONE <sup>®</sup> Trocar Hybrid 12mm cannula Standard <i>X-ONE<sup>®</sup> Hybrid Trocar 12mm Standard cannula</i>	805511288K01010101LW
300-RFS12	X-ONE <sup>®</sup> Trocar Hybrid 12mm cannula Corta <i>X-ONE<sup>®</sup> Hybrid Trocar 12mm Short cannula</i>	805511288K01010101LW
300-RF15	X-ONE <sup>®</sup> Trocar Hybrid 15mm cannula Standard <i>X-ONE<sup>®</sup> Hybrid Trocar 15mm Standard cannula</i>	805511288K01010101LW
301-RF5	X-ONE <sup>®</sup> Kit Trocar Hybrid 5mm - 2 cannule Standard <i>X-ONE<sup>®</sup> Kit Hybrid trocar 5mm – 2 Standard cannulas</i>	805511288K01010101LW
301-RF5/3	X-ONE <sup>®</sup> Kit Trocar Hybrid 5/3mm - 2 cannule Standard <i>X-ONE<sup>®</sup> Kit Hybrid trocar 5/3mm – 2 Standard cannulas</i>	805511288K01010101LW
301-RFS5	X-ONE <sup>®</sup> Kit Trocar Hybrid 5mm - 2 cannule Corte <i>X-ONE<sup>®</sup> Kit Hybrid trocar 5mm – 2 Short cannulas</i>	805511288K01010101LW
301-RFS5/3	X-ONE <sup>®</sup> Kit Trocar Hybrid 5/3mm - 2 cannule Corte <i>X-ONE<sup>®</sup> Kit Hybrid trocar 5/3mm – 2 Short cannulas</i>	805511288K01010101LW
301-RF11	X-ONE <sup>®</sup> Kit Trocar Hybrid 11mm - 2 cannule Standard <i>X-ONE<sup>®</sup> Kit Hybrid trocar 11mm – 2 Standard cannulas</i>	805511288K01010101LW
301-RF12	X-ONE <sup>®</sup> Kit Trocar Hybrid 12mm - 2 cannule Standard <i>X-ONE<sup>®</sup> Kit Hybrid trocar 12mm – 2 Standard cannulas</i>	805511288K01010101LW
301-RFS12	X-ONE <sup>®</sup> Kit Trocar Hybrid 12mm - 2 cannule Corte <i>X-ONE<sup>®</sup> Kit Hybrid trocar 12mm – 2 Short cannulas</i>	805511288K01010101LW
301-RF15	X-ONE <sup>®</sup> Kit Trocar Hybrid 15mm - 2 cannule Standard <i>X-ONE<sup>®</sup> Kit Hybrid trocar 15mm – 2 Standard cannulas</i>	805511288K01010101LW
302-5	X-ONE <sup>®</sup> Kit 2 cannule 5mm Standard <i>X-ONE<sup>®</sup> Kit 2 Standard cannulas 5mm</i>	805511288K01010101LW
302-5/3	X-ONE <sup>®</sup> Kit 2 cannule 5/3mm Standard <i>X-ONE<sup>®</sup> Kit 2 Standard cannulas 5/3mm</i>	805511288K01010101LW
302-S5	X-ONE <sup>®</sup> Kit 2 cannule 5mm Corte <i>X-ONE<sup>®</sup> Kit 2 Short cannulas 5mm</i>	805511288K01010101LW
302-S5/3	X-ONE <sup>®</sup> Kit 2 cannule 5/3mm Corte <i>X-ONE<sup>®</sup> Kit 2 Short cannulas 5/3mm</i>	805511288K01010101LW
302-L5	X-ONE <sup>®</sup> Kit 2 cannule 5mm Lunghe <i>X-ONE<sup>®</sup> Kit 2 Long cannulas 5mm</i>	805511288K01010101LW
302-L5/3	X-ONE <sup>®</sup> Kit 2 cannule 5/3mm Lunghe <i>X-ONE<sup>®</sup> Kit 2 Long cannulas 5/3mm</i>	805511288K01010101LW
302-11	X-ONE <sup>®</sup> Kit 2 cannule 11mm Standard <i>X-ONE<sup>®</sup> Kit 2 Standard cannulas 11mm</i>	805511288K01010101LW
302-12	X-ONE <sup>®</sup> Kit 2 cannule 12mm Standard <i>X-ONE<sup>®</sup> Kit 2 Standard cannulas 12mm</i>	805511288K01010101LW
302-S12	X-ONE <sup>®</sup> Kit 2 cannule 12mm Corte <i>X-ONE<sup>®</sup> Kit 2 Short cannulas 12mm</i>	805511288K01010101LW
302-L12	X-ONE <sup>®</sup> Kit 2 cannule 12mm Lunghe <i>X-ONE<sup>®</sup> Kit 2 Long cannulas 12mm</i>	805511288K01010101LW
302-15	X-ONE <sup>®</sup> Kit 2 cannule 15mm Corta <i>X-ONE<sup>®</sup> Kit 2 Short cannulas 15mm</i>	805511288K01010101LW
302-1-5	X-ONE <sup>®</sup> Cannula singola 5mm Standard <i>X-ONE<sup>®</sup> Single Standard cannula 5mm</i>	805511288K01010101LW



CODICE DI VENDITA <i>Sales Code</i>	Nome commerciale / CARATTERISTICHE <i>Commercial name / FEATURES</i>	UDI-DI di base <i>Basic UDI- DI</i>
302-1-5/3	X-ONE® Cannula singola 5/3mm Standard <i>X-ONE® Single Standard cannula 5/3mm</i>	805511288K01010101LW
302-1-S5	X-ONE® Cannula singola 5mm Corta <i>X-ONE® Single Short cannula 5mm</i>	805511288K01010101LW
302-1-S5/3	X-ONE® Cannula singola 5/3mm corta <i>X-ONE® Single Short cannula 5/3mm</i>	805511288K01010101LW
302-1-L5	X-ONE® Cannula singola 5mm Lunga <i>X-ONE® Single Long cannula 5mm</i>	805511288K01010101LW
302-1-L5/3	X-ONE® Cannula singola 5/3mm Lunga <i>X-ONE® Single Long cannula 5/3mm</i>	805511288K01010101LW
302-1-8	X-ONE® Cannula singola 8mm Standard <i>X-ONE® Single Standard cannula 8mm</i>	805511288K01010101LW
302-1-11	X-ONE® Cannula singola 11mm Standard <i>X-ONE® Single Standard cannula 11mm</i>	805511288K01010101LW
302-1-12	X-ONE® Cannula singola 12mm Standard <i>X-ONE® Single Standard cannula 12mm</i>	805511288K01010101LW
302-1-S12	X-ONE® Cannula singola 12mm Corta <i>X-ONE® Single Short cannula 12mm</i>	805511288K01010101LW
302-1-L12	X-ONE® Cannula singola 12mm Lunga <i>X-ONE® Single Long cannula 12mm</i>	805511288K01010101LW
302-1-15	X-ONE® Cannula singola 15mm Standard <i>X-ONE® Single Standard cannula 15mm</i>	805511288K01010101LW
303-1-V5	X-ONE® Mandrino Ottico singolo 5mm <i>X-ONE® Single Optical Obturator 5mm</i>	805511288K01010103M2
303-1-V11	X-ONE® Mandrino Ottico singolo 11mm <i>X-ONE® Single Optical Obturator 11mm</i>	805511288K01010103M2
303-1-V12	X-ONE® Mandrino Ottico singolo 12mm <i>X-ONE® Single Optical Obturator 12mm</i>	805511288K01010103M2
300-Vb5	X-ONE® Trocar Ottico 5mm cannula Standard con palloncino <i>X-ONE® Optical Trocar 5mm Standard cannula with balloon</i>	805511288K01010103M2
300-Vb11	X-ONE® Trocar Ottico 11mm cannula Standard con palloncino <i>X-ONE® Optical Trocar 11mm Standard cannula with balloon</i>	805511288K01010103M2
300-Vb12	X-ONE® Trocar Ottico 12mm cannula Standard con palloncino <i>X-ONE® Optical Trocar 12mm Standard cannula with balloon</i>	805511288K01010103M2
300-Hb5	X-ONE® Trocar di Hasson 5mm cannula Standard con palloncino <i>X-ONE® Hasson Trocar 5mm Standard cannula with balloon</i>	805511288K01010102LY
300-Hb11	X-ONE® Trocar di Hasson 11mm cannula Standard con palloncino <i>X-ONE® Hasson Trocar 11mm Standard cannula with balloon</i>	805511288K01010102LY
300-Hb12	X-ONE® Trocar di Hasson 12mm cannula Standard con palloncino <i>X-ONE® Hasson Trocar 12mm Standard cannula with balloon</i>	805511288K01010102LY
300-Hv11	X-ONE® Trocar di Hasson con puntale ottico 11 mm cannula Standard <i>X-ONE® Hasson Trocar with Optical obturator 11 mm Standard cannula</i>	805511288K01010102LY
300-Hv12	X-ONE® Trocar di Hasson con puntale ottico 12mm cannula Standard <i>X-ONE® Hasson Trocar with Optical obturator 12mm Standard cannula</i>	805511288K01010102LY
300-T5	X-ONE® Trocar Toracico 5mm cannula Corta <i>X-ONE® Thoracic trocar 5mm Short cannula</i>	805511288 K01010104 M4
300-T11	X-ONE® Trocar Toracico 11mm cannula Corta <i>X-ONE® Thoracic trocar 11mm Short cannula</i>	805511288 K01010104 M4
300-T12	X-ONE® Trocar Toracico 12mm cannula Corta <i>X-ONE® Thoracic trocar 12mm Short cannula</i>	805511288 K01010104 M4

- Destinati al campo chirurgico, nella chirurgia mininvasiva generale, urologica e ginecologica per interventi in addome di qualsiasi natura e chirurgia toracoscopica,  
*Intended for the surgical field, in minimally invasive general, urological and gynecological surgery for abdominal operations of any nature and thoracoscopic surgery,*
- di classe di rischio IIa, in accordo alla regola 7 Allegato VIII del Regolamento (UE) 2017/745 (MDR),
- *risk class IIa, in accordance with rule 7 Annex VIII of the Regulation (EU) 2017/745 (MDR),*

**dichiara / declares**

sotto la propria totale esclusiva responsabilità, che tali dispositivi:

*under its sole responsibility, that these devices:*

- Sono conformi ai requisiti generali di prestazione e sicurezza ed alle disposizioni Regolamento (UE) 2017/745 e ss.mm.ii. come da Fascicolo Tecnico archiviato presso l'azienda;  
*complies with the general performance and safety requirements and with the provisions of Regulation (EU) 2017/745 and subsequent amendments as per the Technical File stored at the company;*
- Non sono state utilizzate Specifiche Comuni per la conformità del suddetto dispositivo;  
*common Specifications have not been used for the compliance of the aforementioned device;*
- sono fabbricati in accordo al Fascicolo Tecnico n. FT 003 ML, che soddisfa i requisiti di cui all'Allegato IX capo I e III del sopra citato Regolamento, come da Certificato n. CSQ-0003-22, rilasciato dall'Istituto Superiore di Sanità, Organismo Notificato 0373, il 28/12/2022.  
*are manufactured in accordance with the Technical File n. FT 003 ML, which satisfies the requirements of Annex IX chapters I and III of the aforementioned Regulation, as per Certificate no. CSQ-0003-22, issued by the Istituto Superiore di Sanità, Notified Body 0373, on 28/12/2022.*

San Gregorio (RC), 28/12/2022

**MEDI LINE S.r.l.**

Il legale Rappresentante

**Medi Line S.R.L.**  
**CUZZUCOLI ANTONINO**  
Amm. Unico

