



Certificato CE

EC Certificate

n. ECM19MDD010 rev. 0

Rilasciato ai sensi della direttiva 93/42/CEE – Allegato II (escl. p.to 4)
Issued according to 93/42/EEC directive – Annex II (excl. clause 4)

Richiedente

Applicant

Ragione Sociale <i>Company Name</i>	Medistri SA
Sede legale <i>Legal address</i>	Route de l'Industrie 96, case postale 115, 1564 Domdidier
Località <i>Place</i>	Domdidier, Switzerland
Sito produttivo <i>Place of production</i>	Idem
Dispositivo Medico <i>Medical device</i>	Sterile Kits
Identificato come <i>Identified as</i>	Vedi allegato al presente certificato <i>See the annex of this certificate</i>

ECM, Organismo Notificato n° 1282 ha verificato il Sistema Qualità (limitato agli aspetti di fabbricazione relativi alla garanzia ed al mantenimento della sterilità) in accordo all'allegato II (escluso il p.to 4) della direttiva 93/42/CEE e ha rilevato che ne soddisfa i requisiti (art.12).


Si fa riferimento al rapporto di audit di emissione del presente certificato del 3 e 4 Giugno, 2019; rif. piano di certificazione: Medistri 19.05

ECM, Notified Body n° 1282 has verified the Quality System (restricted to the aspects of manufacture concerned with securing and maintaining sterile conditions) in accordance with annex II (excluding clause 4) of the 93/42/EEC directive and found that it meets aforesaid requirements (art.12).

Reference to the audit report related to issue of the present certificate dated June, the 3rd and the 4th, 2019; ref. certification plan: Medistri 19.05

Data di prima emissione* <i>Date of first issue</i>	13/11/2017	Data di emissione <i>Date of issue</i>	01/10/2019
Data di revisione <i>Date of revision</i>	//	Data di scadenza <i>Expiry date</i>	27/05/2024

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(Antonio Bedonni - Legale Rappresentante)

*certificato rilasciato per la prima volta da altro Organismo di Certificazione
certificate issued for the first time by another Certification Body

Questo certificato, compreso l'allegato, può essere riprodotto solo integralmente e senza alcuna variazione
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Ente Certificazione Macchine srl

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Allegato al Certificato CE

Annex to EC Certificate

n. ECM19MDD010 rev. 0

Rilasciato i sensi della direttiva 93/42/CEE – Allegato II (escl. p.to 4)

Issued according to 93/42/EEC directive – Annex II (excl. clause 4)

Elenco dei Dispositivi Medici inclusi in questo certificato

List of Medical Devices included in this certificate

Descrizione <i>Description</i>	Codice NBOG <i>NBOG code</i>	Modello <i>Model</i>
4000000 - Single use Bipolar Cable 5m SOFT STERILE	MD 0106 MD 0301 MDS 7006	Single use Bipolar Cable 5m SOFT - Non-woven swabs 5x5cm
4000020 - Single Use Electrosurgical Bayonet Forceps 16 cm, cable 3m, Tip 1.0 STERILE	MD 1104 MD 0301 MDS 7006	Single Use Electrosurgical Bayonet Forceps 16 cm, cable 3m, Tip 1.0 - Non-woven swabs 5x5cm
4000021 - Single Use Electrosurgical McPherson Forceps 10,2 cm, cable 3m, Tip 1.0 STERILE	MD 1104 MD 0301 MDS 7006	Single Use Electrosurgical McPherson Forceps 10,2 cm, cable 3m, Tip - Non-woven swabs 5x5cm
4000022 - Single Use Electrosurgical Straight Forceps 15 cm, cable 3m, Tip 1.0 STERILE	MD 1104 MD 0301 MDS 7006	Single Use Electrosurgical Straight Forceps 15 cm, cable 3m, Tip 1.0 - Non-woven swabs 5x5cm
4000023 - Single Use Electrosurgical Straight Forceps 20 cm, cable 3m, Tip 1.0 STERILE	MD 1104 MD 0301 MDS 7006	Single Use Electrosurgical Straight Forceps 20 cm, cable 3m, Tip 1.0 - Non-woven swabs 5x5cm
4000024 - Single Use Electrosurgical Angled Forceps 15 cm, cable 3m, Tip 1.0 STERILE	MD 1104 MD 0301 MDS 7006	Single Use Electrosurgical Angled Forceps 15 cm, cable 3m, Tip 1.0 - Non-woven swabs 5x5cm
4000030 - Single use Electrosurgical Adson Forceps 15cm, cable 3m, Tip 0.5 STERILE	MD 1104 MD 0301 MDS 7006	Single use Electrosurgical Adson Forceps 15cm, cable 3m, Tip 0.5 - Non-woven swabs 5x5cm
4000031 - Single use Electrosurgical Bayonet Forceps 20cm, cable 3m, Tip 1.0 STERILE	MD 1104 MD 0301 MDS 7006	Single use Electrosurgical Bayonet Forceps 20cm, cable 3m, Tip 1.0 - Non-woven swabs 5x5cm
4000032 - Single use monopolar cable 3m STERILE	MD 0106 MD 0301 MDS 7006	Single use monopolar cable 3m - Non-woven swabs 5x5cm
4000034 - Pelkmann forceps 25 cm STERILE	MD 0106 MD 0301 MDS 7006	Pelkmann forceps - Non-woven swabs 5x5cm
4000035 - Single use Electrosurgical McPherson Forceps 10.2cm, cable 3m Tip 0.5	MD 1104 MD 0301 MDS 7006	Single use Electrosurgical McPherson Forceps 10.2cm, cable 3m Tip 0.5 - Non-woven swabs 5x5cm
4000036 - Single use Electrosurgical Straight Forceps 15cm AD, cable 3m, Tip 0.5 STERILE	MD 1104 MD 0301 MDS 7006	Single use Electrosurgical Straight Forceps 15cm AD, cable 3m, Tip 0.5 - Non-woven swabs 5x5cm
4000045 - Backhaus forceps STERILE	MD 0106 MD 0301 MDS 7006	Backhaus Forceps - Non-woven swabs 5x5cm
4000047 - Single use Electrosurgical McPherson Forceps 10.2 cm, cable 3m, Tip 0.25 STERILE	MD 1104 MD 0301 MDS 7006	Single use Electrosurgical McPherson Forceps 10.2 cm, cable 3m, Tip 0.25 - Non-woven swabs 5x5cm

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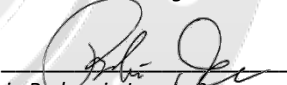
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4000049 - Single Use Monopolar Cable 5m SOFT STERILE	MD 0106 MD 0301 MDS 7006	Single Use Monopolar Cable 5m SOFT - Non-woven swabs 5x5cm
4000050 - Single Use Electrosurgical McPherson Forceps 10.2 cm, cable 5m, Tip 0.5 STERILE	MD 1104 MD 0301 MDS 7006	Single Use Electrosurgical McPherson Forceps 10.2 cm, cable 5m, Tip 0.5 - Non-woven swabs 5x5cm
4000064 - Pozzi forceps STERILE	MD 0106 MD 0301 MDS 7006	Pozzi Forceps - Non-woven swabs 5x5cm
4000067 - Single Use Electrosurgical Straight Forceps Angled Down 15 cm, cable 5m, Tip 0.5 STERILE	MD 1104 MD 0301 MDS 7006	Single Use Electrosurgical Straight Forceps Angled Down 15 cm, cable 5m, Tip 0.5 - Non-woven swabs 5x5cm
4000068 - Single use Bipolar Cable 3m SOFT STERILE	MD 0106 MD 0301 MDS 7006	Single use Bipolar Cable 3m SOFT - Non-woven swabs 5x5cm
4000089 - Single Use Electrosurgical Straight Forceps, Angled Down 20 cm, cable 5m SOFT, Tip 0.5 STERILE	MD 1104 MD 0301 MDS 7006	Single Use Electrosurgical Straight Forceps, Angled Down 20 cm, cable 5m SOFT, Tip 0.5 - Non-woven swabs 5x5cm
4000075 - Set Tunnel Carpien Clinique St-Anne	MD 1104 MD 0301 MD 0301 MDS 7006	Gross Maier Sponge Forceps 20cm BP Handle #3 Scalpel Handle 13.5cm Reynolds/Stevens/Jameson Dissecting Scissors Fine 15cm Blunt Webster Needle Holder Str Smooth Jaws 12.5cm Gillies Skin Hook Retractors 2.3mm, small 18cm Baby Senn-Miller Retractor 8x7mm, 22x7mm, 15.5cm Single Use Electrosurgical Straight Forceps 15 cm, cable 3m, Tip 1.0 Foliodrape Protect 50x50cm Adson Tissue Forceps 1x2 Teeth 12cm Langenbeck Retractor Double

Data di revisione //
Date of revision

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(Antonio Bedonni - Legale Rappresentante)

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