VERTImas iš anglų k.

n. **ECM18MDD016 rev.1**

Data di prima emissione *Išduotas dokumentas*	*15/10/2018*
Data di emissione *Galioja nuo*	*15/10/2018*
Data di ultimo rinnovo *Date of last renewal*	*//*
Data di revisione *Peržiūrėtas dokumentas*	*22/06/2020*
Data di scadenza *Galioja iki*	*14/04/2024*

Certificato CE

EC Sertifikatas

Rilasciato ai sensi della direttiva 93/42/CEE – Allegato II (escl. punto 4)
Išduot pagal direkyvą 93/42/EEC – Annex II (priedas 4)

Richiedente
Applicant

Ragione Sociale *Įmonė*	Eon Meditech Private Limited
Sede legale *adresas*	12, Gurukrupa Society, Utran Road, Utran, Surat
Località *Vieta*	Gujarat India
Sito produttivo *Gamybos vieta*	BL 54, 127, 129, Khanpur Road, Mirapur, Kamrej, Surat -394320, Gujarat India
Dispositivo Medico *Medicinos prietaisas*	Ausies ventiliaciniai vamzdeliai, nosies produktai , PVA tamponai, ANG instrumentai
Identificato come *Priskirtas*	Vedi allegato al presente certificato *Žiūrėti priedą*

ECM, Organismo Notificato n° 1282 ha verificato il Sistema Qualità in accordo all'allegato II (escluso punto 4) della direttiva 93/42/CEE) e ha rilevato che ne soddisfa i requisiti.
Si fa riferimento al rapporto di audit di emissione del presente certificato del 8 aprile 2020; rif. piano di certificazione: Eon-17.07

ECM, notifikuotoji įstaiga Nr. 1282, patikrino kokybės sistemą pagal 93/42/EEB direktyvos II priedą (išskyrus 4 punktą) ir nustatė, kad ji atitinka pirmiau nurodytus reikalavimus.
Nuoroda į audito ataskaitą, susijusią su šio sertifikato išdavimu, 2020 m. balandžio 8 d.; ref. sertifikavimo planas: Eon-07.17

Firma autorizzata
Authorized signature

(Antonio Bedonni - Legale Rappresentante)

Questo certificato, compreso l'allegato (se presente), può essere riprodotto solo integralmente e senza alcuna variazione

Allegato al Certificato CE

Priedas EC sertifikato

Rilasciato ai sensi della direttiva 93/42/CEE – Allegato II (escl. punto 4)
Išduot pagal direkyvą 93/42/EEC – Annex II (excl. clause 4)

Elenco dei Dispositivi Medici inclusi in questo certificato
List of Medical Devices included in this certificate

Ear Ventilation Tubes, class IIa sterile ; NBOG code: MD0106 + MDS7006
Product names:

Tita-prosthesis Vent Tube type Collar Button (ref. 1104)	Tita-prosthesis Vent Tube type Collar Button (ref. 1105)	Tita-prosthesis Vent Tube type Collar Button (ref. 1106)
Shepard - Titanium	Shepard	Shepard with wire
Shepard Blue	Shepard Blue With Wire	Shepard with tail
Shepard Blue with tail	Mini Shepard	Mini Shepard With Wire
Mini Shepard Blue	Mini Shepard Blue With Wire	Mini Shepard with tail
Mini Shepard Blue with tail	Collar Button (ref. 2123)	Collar Button – Blue (ref. 2123B)
Collar Button - With Tail (ref. 2123T)	Collar Button (ref. 2125)	Collar Button – Blue (ref. 2125B)
Collar Button - With Tail (ref. 2125T)	Shah	Shah With wire
Shah Blue	Shah Blue With Tail	Shah Blue With wire
Shah with Tail	Mini Shah	Mini Shah with tail
Mini Shah Blue	Mini Shah with wire	Armstrong
Armstrong Blue	Armstron with Tail	Modified Armstrong
Modified Armstrong Blue	Modified Armstrong with tail	Bevel Bobbin
Bevel Bobbin Blue	Baxter Beveled Bobbin	Baxter Beveled Bobbin Blue
Reuter Bobbin	Reuter Bobbin Blue	Straight Tube
Donaldson	Donaldson Blue	Donaldson(Silicone)
Paparella		

Brand name: Osseous, ORLEON, SALIENT, Myrovent, VentTube

Rhinology Products, class IIa sterile; NBOG code: NBOG code: MD0106 + MDS7006
Product names:

Silicone Sheets (Thickness: 3.00mm)	Silicone Sheets (Thickness: 5.00mm)	Silicone Sheets (Thickness: 0.13mm)
Silicone Sheets (Thickness: 0.25mm)	Silicone Sheets (Thickness: 0.50mm)	Silicone Sheets (Thickness: 1.00mm)
Internal Nasal Airways Splint - Standard	Internal Nasal Airways Splint - Large	Internal Nasal Pre-Cut Splint
Internal Nasal Bi-valve Splint – Standard (ref. 3148SS)	Internal Nasal Bi-valve Splint - Thick	Internal Nasal Bi-valve Splint – Standard (ref. 3148FS)
Internal Nasal Bi-valve Splint - Thin	Internal Nasal Bi-valve Splint - Standard Pediatric	Internal Nasal Bi-valve Splint - Thin Pediatric

Brand name: Osseous, ORLEON, SALIENT, RhinoAid, RhinoSurg

Rhinology Products, class Is sterile; NBOG code: NBOG code: MD0106 + MDS7006
Product names:

External Aluminium Splints - Small	External Aluminium Splints - Medium	External Aluminium Splints - Large
External Thermoplastic Splint - Small	External Thermoplastic Splint - Medium	External Thermoplastic Splint - Large
Epistaxis Balloon Catheter (Intra-Pack)	Epistaxis Balloon Catheter (Post-Pack)	Epistaxis Balloon Catheter (Double Balloon)

Brand name: Osseous, ORLEON, SALIENT, RhinoAid, RhinoSurg

PVA Dressing Packs, class Is ; NBOG code: MD0301 + MDS7006

Product names:

Ear wick (9.0 Dia.x15.0) mm	Ear wick (9.0 Dia.x24.0) mm	Ear Pack (12.0Dia.x15.0)mm
Ear Pack (12.0Dia.x24.0)mm	Ear Pack with string (9.0 Dia.x15.0 mm)	Ear Pack with string (9.0 Dia.x24.0 mm)
Ear Pack with String (12.0Dia.x15.0)mm	Ear Pack with String (12.0Dia.x24.0)mm	Ear wick Fenestrated (9.0 Dia.x15.0) mm
Ear wick Fenestrated (9.0 Dia.x24.0) mm		

Brand name: Osseous, ORLEON, SALIENT, Otopack, Otocel

Product names:

Nasal Dressing without String (4.5x1.5x2.0)cm	Nasal Pack with String (4.5x1.5x2.0)cm	Nasal pack with string & Tube (4.5x1.5x2.0)cm
Nasal Dressing Thin (4.5x1.0x2.0)cm	Nasal Pack without String (8.0x1.5x2.0)cm	Nasal Pack with String (8.0x1.5x2.0)cm
Nasal pack with string & Tube (8.0x1.5x2.0)cm	Nasal Dressing Thin (8.0x1.0x2.0)cm	Epistaxis Nasal Dressing without String (10.0x1.5x2.5)cm
Epistaxis Nasal Dressing with String (10.0x1.5x2.5)cm	Epistaxis Nasal Dressing with String & Tube (10.0x1.5x2.5)cm	Epistaxis Nasal Dressing Thin (10.0x1.0x2.5)cm
Nasal pack Anatomical with string (8.0x1.5x3.0)cm	Nasal pack Anatomical with string & tube (8.0x1.5x3.0)cm	Nasal Anatomical Pack Thin (8.0x1.0x2.0)cm
Sinus Pack (3.5x1.2x0.6)cm	Sinus Pack (3.5x1.2x0.9)cm	Epistaxis Nasal Dressing Pediatric (5.5x1.0x2.5)cm

Brand name: Osseous, ORLEON, SALIENT, Nasopack, Nasocel

Ent Instruments, suction tubes class IIa sterile; NBOG code: MD0106 + MDS7006

Product names:

Suction Tube for Ear-Disposable (2.0Dia.x100.0)mm	Suction Tube for Ear-Disposable (1.6Dia.x100.0)mm	Suction Tube for Ear-Disposable (1.4Dia.x100.0)mm
Suction Tube for Ear-Disposable(1.2Dia.x100.0)mm	Suction Tube for Ear-Disposable (1.0Dia.x100.0)mm	Suction Tube for Ear-Disposable (0.9Dia.x100.0)mm
Suction Tube for Ear-Disposable (0.7Dia.x100.0)mm	Suction Tube for Ear-Disposable (0.5Dia.x100.0)mm	Suction Tube for Ear-Disposable (2.0Dia.x60.0)mm
Suction Tube for Ear-Disposable (2.0Dia.x70.0)mm	Suction Tube for Ear-Disposable (2.0Dia.x80.0)mm	Suction Tube for Ear-Disposable (1.4Dia.x80.0)mm
Suction Tube for Ear-Disposable (1.4Dia.x70.0)mm	Suction Tube for Ear-Disposable (1.4Dia.x60.0)mm	Suction Tube for Ear-Disposable (1.2Dia.x70.0)mm
Suction Tube for Ear-Disposable (1.0Dia.x80.0)mm	Suction Tube for Ear-Disposable (1.0Dia.x70.0)mm	Suction Tube for Ear-Disposable (1.0Dia.x60.0)mm
Suction Tube for Ear-Disposable (0.8Dia.x70.0)mm	Suction Tube for Ear-Disposable (0.7Dia.x80.0)mm	Suction Tube for Ear-Disposable (0.7Dia.x70.0)mm
Suction Tube for Ear-Disposable (0.7Dia.x60.0)mm	Suction Tube for Ear-Disposable (0.6Dia.x70.0)mm	Suction Tube for Ear-Disposable (0.4Dia.x80.0)mm
Suction Tube for Ear-Disposable (0.4Dia.x70.0)mm	Suction Tube for Ear-Disposable (0.4Dia.x60.0)mm	Suction Tube for Ear-Reusable (0.4Dia.x60.0)mm
Suction Tube for Ear-Reusable (0.4Dia.x70.0)mm	Suction Tube for Ear-Reusable (0.4Dia.x80.0)mm	Suction Tube for Ear-Reusable (0.6Dia.x70.0)mm
Suction Tube for Ear-Reusable (0.7Dia.x70.0)mm	Suction Tube for Ear-Reusable (0.7Dia.x80.0)mm	Suction Tube for Ear-Reusable (0.8Dia.x70.0)mm
Suction Tube for Ear-Reusable (1.0Dia.x70.0)mm	Suction Tube for Ear-Reusable (1.2Dia.x70.0)mm	Suction Tube for Ear-Reusable (1.2Dia.x100.0)mm
Suction Tube for Ear-Reusable (1.4Dia.x70.0)mm	Suction Tube for Ear-Reusable (1.4Dia.x80.0)mm	Suction Tube for Ear-Reusable (1.6Dia.x70.0)mm
Suction Tube for Ear-Reusable (1.7Dia.x70.0)mm	Suction Tube for Ear-Reusable (2.0Dia.x70.0)mm	Suction Tube for Ear-Reusable (2.0Dia.x100.0)mm
Suction Tube for Ear-Reusable (2.5Dia.x80.0)mm	Suction Tube for Ear-Reusable (3.0Dia.x80.0)mm	Suction Tube for Nose-Disposable (2.0Dia.x100.0)mm
Suction Tube for Nose-Disposable (2.0Dia.x120.0)mm	Suction Tube for Nose-Disposable (2.0Dia.x140.0)mm	Suction Tube for Nose-Disposable (2.0Dia.x160.0)mm
Suction Tube for Nose-Disposable (3.0Dia.x100.0)mm	Suction Tube for Nose-Disposable (3.0Dia.x120.0)mm	Suction Tube for Nose-Disposable (3.0Dia.x140.0)mm

Suction Tube for Nose-Disposable (3.0Dia.x160.0)mm	Suction Tube for Nose-Disposable (3.5Dia.x120.0)mm	Suction Tube for Nose-Disposable (3.5Dia.x140.0)mm
Suction Tube for Nose-Disposable (3.5Dia.x160.0)mm	Suction Tube for Nose-Disposable (4.0Dia.x100.0)mm	Suction Tube for Nose-Disposable (4.0Dia.x120.0)mm
Suction Tube for Nose-Disposable (4.0Dia.x140.0)mm	Suction Tube for Nose-Disposable (4.0Dia.x160.0)mm	Suction Tube for Nose-Disposable (5.0Dia.x120.0)mm
Suction Tube for Nose-Disposable (5.0Dia.x140.0)mm	Suction Tube for Nose-Disposable (5.0Dia.x160.0)mm	Suction Tube for Nose-Disposable (2.0Dia.x150.0)mm
Suction Tube for Nose-Disposable (3.0Dia.x150.0)mm	Suction Tube for Nose-Disposable (4.0Dia.x150.0)mm	Suction Tube for Nose-Reusable-Right (2.0Dia.x120.0)mm
Suction Tube for Nose-Reusable-Left (2.0Dia.x120.0)mm	Suction Tube for Nose-Reusable-Right (2.0Dia.x140.0)mm	Suction Tube for Nose-Reusable-Left (2.0Dia.x140.0)mm
Suction Tube for Nose-Reusable-Right (2.0Dia.x160.0)mm	Suction Tube for Nose-Reusable-Left (2.0Dia.x160.0)mm	Suction Tube for Nose-Reusable-Right (2.5Dia.x120.0)mm
Suction Tube for Nose-Reusable-Left (2.5Dia.x120.0)mm	Suction Tube for Nose-Reusable-Right (2.5Dia.x140.0)mm	Suction Tube for Nose-Reusable-Left (2.5Dia.x140.0)mm
Suction Tube for Nose-Reusable-Right (2.5Dia.x160.0)mm	Suction Tube for Nose-Reusable-Left (2.5Dia.x160.0)mm	Suction Tube for Nose-Reusable-Right (3.0Dia.x120.0)mm
Suction Tube for Nose-Reusable-Left (3.0Dia.x120.0)mm	Suction Tube for Nose-Reusable-Right (3.0Dia.x140.0)mm	Suction Tube for Nose-Reusable-Left (3.0Dia.x140.0)mm
Suction Tube for Nose-Reusable-Right (3.0Dia.x160.0)mm	Suction Tube for Nose-Reusable-Left (3.0Dia.x160.0)mm	Suction Tube for Nose-Reusable-Right (3.5Dia.x120.0)mm
Suction Tube for Nose-Reusable-Left (3.5Dia.x120.0)mm	Suction Tube for Nose-Reusable-Right (3.5Dia.x140.0)mm	Suction Tube for Nose-Reusable-Left (3.5Dia.x140.0)mm
Suction Tube for Nose-Reusable-Right (3.5Dia.x160.0)mm	Suction Tube for Nose-Reusable-Left (3.5Dia.x160.0)mm	Suction Tube for Nose-Reusable-Right (4.0Dia.x120.0)mm
Suction Tube for Nose-Reusable-Left (4.0Dia.x120.0)mm	Suction Tube for Nose-Reusable-Right (4.0Dia.x140.0)mm	Suction Tube for Nose-Reusable-Left (4.0Dia.x140.0)mm
Suction Tube for Nose-Reusable-Right (4.0Dia.x160.0)mm	Suction Tube for Nose-Reusable-Left (4.0Dia.x160.0)mm	Suction Tube for Nose-Reusable-Right (5.0Dia.x120.0)mm
Suction Tube for Nose-Reusable-Left (5.0Dia.x120.0)mm	Suction Tube for Nose-Reusable-Right (5.0Dia.x140.0)mm	Suction Tube for Nose-Reusable-Left (5.0Dia.x140.0)mm
Suction Tube for Nose-Reusable-Right (5.0Dia.x160.0)mm	Suction Tube for Nose-Reusable-Left (5.0Dia.x160.0)mm	Suction Tube for Throat-Disposable (2.0Dia.x250.0)mm
Suction Tube for Throat-Disposable (3.0Dia.x250.0)mm	Suction Tube for Sinus-Disposable (2.5Dia.x150.0)mm	Suction Tube for Sinus-Disposable (3.0Dia.x150.0)mm
Suction Tube for Sinus-Disposable (4.0Dia.x150.0)mm		

Brand name: Osseous, ORLEON, SALIENT, Sucto, AidEon

Ent Instruments, burs class IIa; NBOG code: MD0106

Product names:

Burs-stainless Steel-0.5mm	Burs-stainless Steel-1.0mm	Burs-stainless Steel-1.5mm
Burs-stainless Steel-2.0mm	Burs-stainless Steel-2.5mm	Burs-stainless Steel-3.0mm
Burs-stainless Steel-3.5mm	Burs-stainless Steel-4.0mm	Burs-stainless Steel-4.5mm
Burs-stainless Steel-5.0mm	Burs-stainless Steel-5.5mm	Burs-stainless Steel-6.0mm
Burs-stainless Steel-6.5mm	Burs-stainless Steel-7.0mm	Burs-Tungsten Carbide-0.5mm
Burs-Tungsten Carbide-1.0mm	Burs-Tungsten Carbide-1.5mm	Burs-Tungsten Carbide-2.0mm
Burs-Tungsten Carbide-2.5mm	Burs-Tungsten Carbide-3.0mm	Burs-Tungsten Carbide-3.5mm
Burs-Tungsten Carbide-4.0mm	Burs-Tungsten Carbide-4.5mm	Burs-Tungsten Carbide-5.0mm
Burs-Tungsten Carbide-5.5mm	Burs-Tungsten Carbide-6.0mm	Burs-Tungsten Carbide-6.5mm
Burs-Tungsten Carbide-7.0mm	Burs-Fine Diamond-0.5mm	Burs-Fine Diamond-1.0mm
Burs-Fine Diamond-1.5mm	Burs-Fine Diamond-2.0mm	Burs-Fine Diamond-2.5mm
Burs-Fine Diamond-3.0mm	Burs-Fine Diamond-3.5mm	Burs-Fine Diamond-4.0mm
Burs-Fine Diamond-4.5mm	Burs-Fine Diamond-5.0mm	Burs-Fine Diamond-6.0mm
Burs-Course Diamond-0.5mm	Burs-Course Diamond-1.0mm	Burs-Course Diamond-1.5mm
Burs-Course Diamond-2.0mm	Burs-Course Diamond-2.5mm	Burs-Course Diamond-3.0mm
Burs-Course Diamond-3.5mm	Burs-Course Diamond-4.0mm	Burs-Course Diamond-4.5mm
Burs-Course Diamond-5.0mm	Burs-Course Diamond-6.0mm	

Brand name: Osseous, ORLEON, SALIENT, Gyro, Roton

Ent Instruments, blades class IIa; NBOG code: MD0106
Product names:

Blades-Straight Sinus Blades	Blades-Curved Sinus Blades - 40	Blades-Curved Sinus Blades - 60
Blades-Tonsillectomy and adenoidectomy Blades		

Brand name: Osseous, ORLEON, SALIENT, Gyro, Roton

Ent Instruments, suction controller class Is; NBOG code: MD0106 + MDS7006
Product names:

Suction controller		

Brand name: Osseous, ORLEON, SALIENT, Auxilio, AidEon

Laryngology Products; class IIa ; NBOG code: MD0106
Product names:

Laryngectomy Tube-standard-08/36	Laryngectomy Tube-standard-08/55	Laryngectomy Tube-standard-09/36
Laryngectomy Tube-standard-09/55	Laryngectomy Tube-standard-10/36	Laryngectomy Tube-standard-10/55
Laryngectomy Tube-Standard-12/36	Laryngectomy Tube-standard-12/55	Laryngectomy Tube-Fenestrated-08/36
Laryngectomy Tube-Fenestrated-08/55	Laryngectomy Tube-Fenestrated-09/36	Laryngectomy Tube-Fenestrated-09/55
Laryngectomy Tube-Fenestrated-10/36	Laryngectomy Tube-Fenestrated-10/55	Laryngectomy Tube-Fenestrated-12/36
Laryngectomy Tube-Fenestrated-12/55	Laryngectomy Button-12/08	Laryngectomy Button-14/08
Laryngectomy Button-16/08	Laryngectomy Button-18/08	Laryngectomy Button-12/18
Laryngectomy Button-14/18	Laryngectomy Button-16/18	Laryngectomy Button-18/18
Salivary by Pass Tube-Clear-10	Salivary by Pass Tube-Clear-12	Salivary by Pass Tube-Clear-14
Salivary by Pass Tube-White-10	Salivary by Pass Tube-White-12	Salivary by Pass Tube-White-14
Tracheal T-Tube-Clear-standard 31506CS	Tracheal T-Tube-Clear-standard 31508CS	Tracheal T-Tube-Clear-standard 31510CS
Tracheal T-Tube-Clear-standard 31512CS	Tracheal T-Tube-Clear-standard 31514CS	Tracheal T-Tube-Clear-standard 31516CS
Tracheal T-Tube-White-standard 31506WS	Tracheal T-Tube-White-standard 31508WS	Tracheal T-Tube-White-standard 31510WS
Tracheal T-Tube-White-standard 31512WS	Tracheal T-Tube-White-standard 31514WS	Tracheal T-Tube-White-standard 31516WS
Tracheal T-Tube-Clear-Long 31506CL	Tracheal T-Tube-Clear-Long 31508CL	Tracheal T-Tube-Clear-Long 31510CL
Tracheal T-Tube-Clear-Long 31512CL	Tracheal T-Tube-Clear-Long 31514CL	Tracheal T-Tube-Clear-Long 31516CL
Tracheal T-Tube-White-Long 31506WL	Tracheal T-Tube-White-Long 31508WL	Tracheal T-Tube-White-Long 31510WL
Tracheal T-Tube-White-Long 31512WL	Tracheal T-Tube-White-Long 31514WL	Tracheal T-Tube-White-Long 31516WL
Tracheal T-Tube-Clear-Extra Long 31506CE	Tracheal T-Tube-Clear-Extra Long 31508CE	Tracheal T-Tube-Clear-Extra Long 31510CE
Tracheal T-Tube-Clear-Extra Long 31512CE	Tracheal T-Tube-Clear-Extra Long 31514CE	Tracheal T-Tube-White-Extra Long 31506WE
Tracheal T-Tube-White-Extra Long 31508WE	Tracheal T-Tube-White-Extra Long 31510WE	Tracheal T-Tube-White-Extra Long 31512WE
Tracheal T-Tube-White-Extra Long 31514WE		

Brand name: Osseous, ORLEON, SALIENT, VoxEon, VozMed

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(Antonio Bedonni - Legale Rappresentante)

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