



EC-CERTIFICATE

(Full quality assurance system)



This is to certify that the company

Eon Meditech Pvt. Ltd.

Plot No. 12, Gurukrupa Society, Opp. Utran Arogya Kendra,
Utran Road
Surat, Gujarat 394105
India

has implemented and maintains a full quality assurance system which applies to the products at every stage from design to final controls.

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of

Annex II – excluding Section 4 of Council Directive 93/42/EEC concerning medical devices

with respect to the following medical devices:

Sterile Ear Ventilation Tube (T-Tube) ,Sterile Middle Ear Implant (Total ossicular replacement prosthesis (TORP), Partial ossicular replacement prosthesis (PORP), Pistons), Sterile Nasal Septal Button, Sterile and Non-Sterile Umbrella Keels according to annex

The manufacturer is subject to surveillance according to Annex II, Section 5. The CE marking with the Notified Body Identification Number (0297) may be affixed on the devices listed in the certificate. An EC Design Examination Certificate according to Annex II, Section 4 is required for class III devices covered by this certificate. The certificate is in the case of class I(s) devices (I(s) = class I products placed on the market in sterile conditions) limited to the aspects of manufacture concerned with securing and maintaining sterile conditions. The certificate is in the case of class I(m) devices (I(m) = class I devices with a measuring function) limited to the aspects of manufacture concerned with the conformity of the products with the metrological requirements.

Certificate registration no.	544489 MR2
Certificate unique ID	170759886
Effective date	2020-11-13
Expiry date	2024-05-26
Frankfurt am Main	2020-11-13

DQS Medizinprodukte GmbH



Sigrid Uhlemann
Managing Director

Dr. Thomas Feldmann
Head of Certification Body

August-Schanz-Straße 21, 60433 Frankfurt am Main,
Tel. +49 (0) 69 95427-300, medical.devices@dqs-med.de

DQS Medizinprodukte GmbH is a Notified Body according to Council Directive 93/42/EEC concerning medical devices with the Identification Number 0297.



Annex to certificate
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Device Family	Device	Class
Middle Ear Implant	Ref. No. Product Name 1101 Tita-prosthesis type Partial Vario Campana (PORP) 1207 TitaHAp-prosthesis type Vario Partial (PORP) 2133 Fluoroplastic Partial Prosthesis 2141 Fluoroplastic Offset Partial Prosthesis 1102 Tita-prosthesis type Total Vario Cask (TORP) 1208 TitaHAp-prosthesis type Vario Total (TORP) 2134 Fluoroplastic Total Prosthesis 1138 Titanium Universal Middle Ear Prosthesis 2139 Fluoroplastic Universal Middle Ear Prosthesis - Offset 2140 Fluoroplastic Universal Middle Ear Prosthesis - Centered 2142 Fluoroplastic Offset Total Prosthesis 1103 Tita-prosthesis Piston type Loop (PISTON) 1121 Clip Stapes Piston- Titanium 1122 Titanium Stapes Piston with Integrated PTFE Shoe 4119 Tita-PTFE Vario Piston type Loop 9131 Super Titanium Vario Piston type Loop 9132 Super Tita-PTFE Vario Piston type Loop 5120 Super Elastic NITINOL Vario Piston type Loop 8130 Superelastic NITINOL-PTFE Vario Piston type Loop 2127 Fluoroplastic Stapes Piston (Shaft Dia.:0.5mm) 2128 Fluoroplastic Stapes Piston (Shaft Dia.:0.4mm) 2129 Fluoroplastic Stapes Piston (Shaft Dia.:0.6mm) Brand Name : Osseous, ORLEON, SALIENT, Otopros, Otoplants	IIb
Ear Ventilation Tube	Ref. No. Product Name 3115S T Tube(Silicone) (L: 6mm) 3115M T Tube(Silicone) (L: 9mm) 3115L T Tube(Silicone) (L: 12mm) Brand Name : Osseous, ORLEON, SALIENT, MyroVent, VentTube	IIb
Rhinology Products	Ref. No. Product Name 3145S Nasal Septal Button - Standard 3145L Nasal Septal Button - Large 3145E Nasal Septal Button - Elliptical 3145EL Nasal Septal Button - Elliptical Large Brand Name : Osseous, ORLEON, SALIENT, RhinoAid, RhinoSurg	IIa



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Device Family	Device	Class
Laryngology Products	Ref. No. Product Name	IIB
	31212C Umbrella Keel-Clear-12	
	31214C Umbrella Keel-Clear-14	
	31216C Umbrella Keel-Clear-16	
	31212W Umbrella Keel-White-12	
	31214W Umbrella Keel-White-14	
	31216W Umbrella Keel-White-16	
Brand Name : Osseous, ORLEON, SALIENT, VoxEon, VozMed		