

DECLARATION OF CONFORMITY

UID: EMPL/DOC_MEI-01

CE
0297

Name of the Manufacturer

(Name and address)

Eon Meditech Pvt. Ltd.

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

Factory: BL 54, 127, 129, Khanpur Road, Mirapur, Kamrej, Surat -394320, Gujarat India.

Product Category & Products:

Middle Ear Implants (Refer PL-06 for Product details)

Product Classification:

Class IIb According (EU) 2017/745, Annex IX, and Rule No. 8

Conformity Assessment Procedure:

Annex II excl. clause 4 of (EU) 2017/745 Annex IX, and Rule No. 8

EU Representative:

CMC MEDICAL DEVICES & DRUGS S.L.
C/ Horacio Lengo Nº 18, CP 29006, Málaga, Spain.

Email: info@cmcmmedicaldevices.com

Details of Notified Body:

DQS Medizinprodukte GmbH
August-Schanz-Str. 21
60433 Frankfurt am Main
Germany
Notified Body no. 0297

Section 12_Rev 06

Declaration of Conformity

Dated 27.05.2024



EC Certificate No. & Validity:

The CE Certificate number 170759886, originally valid until 26th May 2024, has been extended up to 31/12/2027 for Class IIb products. This extension was granted according to the confirmation letter (Reference: 170759886) from the DQS notified body and the transfer agreement (2023-10-09_AZ544489_EONMeditech_420_55e_Transfer Agreement MDD legacy devices)

Regulation:

REGULATION (EU) 2017/745 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

List of Applicable Standards: EN ISO 13485: 2016, EN ISO 14971:2019, ISO 10993-1:2018, ISO 10993-3:2014, ISO 10993-5:2009, ISO 10993-7:2008/Amd 1:2019, ISO 10993-11:2017, ISO 11135:2014/ Amd 1:2018, EN ISO 15223-1:2021, ISO 20417: 2021 , EN ISO 11137-1:2015, EN ISO 11137-2:2013/Amd 1:2022, EN ISO 11737-1:2018, EN ISO 11737-2:2020, ISO 11607-1:2019/Amd 1:2023, ISO 11607-2:2019/Amd 1:2023

The Devices Meet the General Safety and Performance Requirements as per Annex I of EU MDR 2017/745.

I assure with this to the user of the product for the conformity with the normative documents and I take the responsibility for the characteristics of the product to which this declaration refers.

Place: Surat

Date: 27.05.2024



Technical Director

Mr. Nirav khunt





List of Products: PL-06 : Middle Ear Implants

Date: 27.05.2024

Brands: OSSEOUS, ORLEON, SALIENT, ENTECH, MEDINIQUE

Sr. No.	Type	Ref. No.	Variants	UDI-DI*
1	PORP	E1101	Tita-prosthesis type Partial Vario Campana (PORP)	08906039315332 (01Pc)
		E1207	TitaHAp-prosthesis type Vario Partial (PORP)	08906039315394 (01Pc)
		E2133	Fluoroplastic Partial Prosthesis	08906039315493 (01Pc)
		E2141	Fluoroplastic Offset Partial Prosthesis	08906039315561 (01Pc)
	TORP	E1102	Tita-prosthesis type Total Vario Cask (TORP)	08906039315349 (01Pc)
		E1208	TitaHAp-prosthesis type Vario Total (TORP)	08906039315400 (01Pc)
		E2134	Fluoroplastic Total Prosthesis	08906039315509 (01Pc)
		E1138	Titanium Grade 2 Universal Middle Ear Prosthesis	08906039315585 (01Pc)
		E2139	Fluoroplastic Universal Middle Ear Prosthesis – Offset	08906039315516 (01Pc)
		E2140	Fluoroplastic Universal Middle Ear Prosthesis – Centered	08906039315523 (01Pc)
	PISTON	E2142	Fluoroplastic Offset Total Prosthesis	08906039315578 (01Pc)
		E1103	Tita-prosthesis Piston type Loop (PISTON)	08906039315356 (01Pc)
		E1121	Clip Stapes Piston- Titanium Grade 2	08906039315363 (01Pc)
		E1122	Titanium Grade 2 Stapes Piston with Integrated PTFE Shoe	08906039315370 (01Pc)
		E4119	Tita-PTFE Vario Piston type Loop	08906039315325 (01Pc)
		E9131	Super Titanium Vario Piston type Loop	08906039315417 (01Pc)
		E9132	Super Tita-PTFE Vario Piston type Loop	08906039315424 (01Pc)
		E5120	Super Elastic NITINOL Vario Piston type Loop	08906039315431 (01Pc)
		E8130	Super elastic NITINOL-PTFE Vario Piston type Loop	08906039315448 (01Pc)
	E2127	Fluoroplastic Stapes Piston (Shaft Dia.:0.5mm)	08906039315455 (01Pc)	
E2128	Fluoroplastic Stapes Piston (Shaft Dia.:0.4mm)	08906039315462 (01Pc)		
E2129	Fluoroplastic Stapes Piston (Shaft Dia.:0.6mm)	08906039315479 (01Pc)		

* 14 digits GTIN for secondary packaging.

Dated: 27.05.2024

Mr. Nirav khunt
Technical Director
Eon Meditech Pvt. Ltd.

