DQS Medizinprodukte GmbH | August-Schanz-Str. 21 | 60433 Frankfurt am Main

Eon Meditech Pvt. Ltd.

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

NOTARY S. J. SAVALIA SURAT CITY & DIST. (GUJ.) Reg. No. 20545 EXPIRY DATE 03/03/2025 GOVT. OF INDIA

2023-10-17

Notified Body Confirmation Letter

Reference: 170759886

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical device

This letter confirms that, DQS Medizinprodukte GmbH, a Notified Body designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0297 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Eon Meditech Pvt. Ltd.

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

Gujarat

India

SRN: IN-MF-000014457

Digitally signed by Jighili Tatiana
Date: 2024.08.16 18:03:04 EEST
Reason: MoldSign Signature
Location: Moldova
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The devices covered by the formal application and the written agreement mentioned above are identified in the Tables listed below: Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which DQS Medizinprodukte GmbH is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but DQS Medizinprodukte GmbH has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry, or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,

D. Siuda

Daniel Siuda

Regulatory Affairs Manager

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Middle Ear Implant	Class IIb implantable non- WET device	N/A	Certificate No. – 170759886 DQS 0297
Ear Ventilation Tubes-Silicone	Class IIb implantable non- WET device	N/A	Certificate No. – 170759886 DQS 0297
Nasal Septal Button	Class IIa	N/A	Certificate No. – 170759886 DQS 0297
Ear Ventilation Tubes	Class IIb implantable non- WET device	N/A	Certificate No. n. ECM18MDD016 Rev.1 ECM -1282
Rhinology Products – Internal Nasal Splint	Class IIa	N/A	Certificate No. n. ECM18MDD016 Rev.1 ECM -1282
Rhinology Products – External Nasal Splint	Class I devices placed on the market in sterile condition	N/A	Certificate No. n. ECM18MDD016 Rev.1 ECM -1282
Rhinology Products – Epistaxis Balloon Catheter	Class I devices placed on the market in sterile condition	N/A	Certificate No. n. ECM18MDD016 Rev.1 ECM -1282
PVA Dressing Packs (Ear Wick and Ear Pack)	Class I devices placed on the market in sterile condition	N/A	Certificate No.

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
			n. ECM18MDD016 Rev.1 ECM -1282
Nasal Dressing	Class I devices placed on the market in sterile condition	N/A	Certificate No. n. ECM18MDD016 Rev.1 ECM -1282
Ent Instruments- **Suction Tube (Single use & Reusable)**	Class IIa	N/A	Certificate No. n. ECM18MDD016 Rev.1 ECM -1282
Ent Instruments- **ENT Burs and Blades**	Class IIa	N/A	Certificate No. n. ECM18MDD016 Rev.1 ECM -1282
Ent Instruments- **Suction Controller**	Class I devices placed on the market in sterile condition	N/A	Certificate No. n. ECM18MDD016 Rev.1 ECM -1282
Laryngology Products- **Laryngectomy Tubes,** **Laryngectomy Buttons**	Class IIb implantable non- WET device	N/A	Certificate No. n. ECM18MDD016 Rev.1 ECM -1282

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (as proposed by the manufacturer within the application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023-10-04	544489-1	Initial issue
2023-10-17	544489-2	Switch from Prodcuts to table 1
	Cert-ID	description of change (e.g. removal of device XYZ from Table 2)

NOTARY S. J. SAVALIA Surat City & Dist. (Guj.) Reg. No. 210545 EXPIRY DATE 03/03/2025 GOVT. OF INDIA

TRUE COPY

S. J. SAVALIA
Advocate & Notary
Govt. of India
Surat City & Dist. (Gujarat)