MTIC InterCert S.r.l.
Via Moscova, 11 – 20017 RHO (MI) – ITALY

To **AMRIT CHEMICAL AND MINERAL AGENCY**
F-343, Phase-8b, Industrial Area, Mohali, 160071 Punjab – INDIA
ammdent@hotmail.com

Ns Rif. / Our Ref.	Vs rif. / Your Ref.	Rif. MTIC Nome / Name	Data/ Date
DMP-08-24-07 Rev1	---	P. Badalucco	15/10/2024

Subject: **Notified Body Confirmation Letter**

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 as regards the transitional provisions for certain medical devices

This letter confirms that, MTIC Intercert S.r.l., a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0068 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:

Amrit Chemical and Mineral Agency
F-343, Phase-8b, Industrial Area, Mohali, 160071 Punjab – INDIA
SRN Number: not available

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below.
Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB 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 the NB 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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the Manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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 Reg. (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
MTIC Intercert S.r. l.
Area Manager – Medical Devices
Ing. Pietro Badalucco

MTIC InterCert S.r.l.
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Capitale Sociale Euro 26.000,00 I.V. – C.F./P.IVA/n. registrazione Reg. Impr. 00862210150 - R.E.A. Milano 798508

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 or Basic UDI-DI (under MDR 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
Dental materials and accessories Models: LC Cal Excel; D-pulp; Prepcanal; CAVLAQ / PROVAR; Seal Plus; PC Seal; Frost; Canalsolve / CanalsolveR; Sodium Hypochlorite; Calcium Hydroxide; Orthodontic adhesive system; MTA (Mineral Trioxide aggregate); Dual core; Pit & Fissure sealant; Zinogen; Premium / Regular GI Fill / GI Core; Premium GI Luting; Nano fill dental bond; Canalarge; Resino Seal; Endoflux (formulation change); Ultrawhite; Prolax; Citocid (Citric acid sol.); Zinc oxide / Eugenol Cement; D-Hydral; L C G I Line; Nanofill; Flowable; CAVITEMP; Zinc Phosphate cement; Tempting; Basic UDI-DI: **not available**	IIa	NA	Nr. 0068/QPZ-DM/413-2021 First issue date: 25/05/2021 Expiration date: 27/05/2024 MTIC Intercert Srl (NB 0068)

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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 or Basic UDI-DI (under MDR 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
NA	NA	NA	NA

TABLE 3:

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-08-23	DMP-08-24-07	Initial issue
2024-10-15	DMP-08-24-07 rev1	Revision issued to report in table the exact nr. of EC certificate "0068/QPZ-DM/413-2021" instead of "0068/QCO-DM/413-2021"

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