Ente Certificazione Macchine

Notified Body n. 1282 - Testing Laboratory – Nr. 121697 PJLA
Authorized Training Body n. 6737 - Inspection Body

CONFIRMATION LETTER IN THE FRAMEWORK OF REGULATION EU 2023/607

FOR "LEGACY" DEVICES ACCORDING TO DIRECTIVE 93/42/EEC

REFERENCE N° 151/F

ENTE CERTIFICAZIONE MACCHINE SRL
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ENTE CERTIFICAZIONE MACCHINE

Prexa Industries (Private) Limited

Address: 2km Kingra Road Kakaywali Sialkot 51310, Pakistan
Referent: Mr. Haroon Ahmed Chughtai

CONFIRMATION LETTER IN THE FRAMEWORK OF REGULATION EU 2023/607

FOR "LEGACY" DEVICES
ACCORDING TO DIRECTIVE 93/42/EEC

Confirmation of the status of a formal application, written agreement, and appropriate surveillance activity 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 devices

Ente Certificazione Macchine srl (ECM), a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **1282 on NANDO**, confirms to have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and to have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with **Prexa Industries (Private) Limited.**

In addition, this letter confirms that **ECM**, where relevant, has signed a written agreement with **Prexa Industries (Private) Limited** governing transfer of the surveillance activitiy in accordance with Article 120, paragraph 3e of MDR as amended by Regulation (EU) 2023/607.

The devices covered by the formal application and the written agreements mentioned above are identified in the Tables below. **Table 1** identifies devices for which an MDR application has been received, written agreement concluded, and for which **ECM** is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. **Table 2** identifies devices for which an MDR application has been received and a written agreement concluded, but **ECM** 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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 repectively, by 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 120.3 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)

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

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

Device name	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application
Reusable Surgical Instruments Variants: 1. Scissors 2. Surgical Knives/Scalpel 3. Curettes 4. Needle Guides Forceps 5. Tweezers 6. Needle Holder 7. Retractors 8. Probes 9. Dilators & Sounds 10. Suction Cannula	☐ Class IIb device ☐ Class IIa device ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☒ Class I devices that qualify as re-usable surgical instruments	☐ MDD/AIMDD device identification: ☒ Not applicable	☐ MDD/AIMDD Certificate Certificate number issued by NB name and NANDO number ☒ Not applicable
Single Use Sterile and non-sterile surgical instruments Variants: 1. Scissors 2. Surgical Knives/scalpel 3. Curettes 4. Needle guides	☐ Class IIb device ☒ Class IIa device ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments	☐ MDD/AIMDD device identification: ☒ Not applicable	☐ MDD/AIMDD Certificate Certificate number issued by NB name and NANDO number ☒ Not applicable
Single Use Sterile and non-sterile surgical instruments Variants: 1. Tweezers 2. Forceps 3. Needle Holders 4. Probes 5. Dilators 6. Sounds	☐ Class IIb device ☒ Class IIa device ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function	☐ MDD/AIMDD device identification: ☒ Not applicable	☐ MDD/AIMDD Certificate Certificate number issued by NB name and NANDO number ☒ Not applicable

Device name	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application
	☐ Class I devices that qualify as re-usable surgical instruments		
Single Use Sterile and non-sterile surgical instruments Retractors	☐ Class IIb device ☒ Class IIa device ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments	☐ MDD/AIMDD device identification: ☒ Not applicable	☐ MDD/AIMDD Certificate Certificate number issued by NB name and NANDO number ☒ Not applicable
Single Use Sterile and non-sterile surgical instruments Variants: 1. Suction Cannula 2. Tubes	☐ Class IIb device ☒ Class IIa device ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments	☐ MDD/AIMDD device identification: ☒ Not applicable	☐ MDD/AIMDD Certificate Certificate number issued by NB name and NANDO number ☒ Not applicable