

EC Certificate Full Quality Assurance System: Certificate PK19/818842627

The management system of

Tecno Instruments Pvt. Ltd.

316-C Small Industrial Estate Sialkot - 51340, Pakistan

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on medical devices, Annex II (excluding Section 4)

For the following products

Bipolar Forceps Reusable, Monopolar Forceps / Diathermy Inst Reusable, Bipolar Forceps sterile Single use w/wo cable, Monopolar Forceps Sterile Single use w/wo cable, Finger Switch Pencil Reusable, Finger Switch Pencil sterile single use, Electrosurgical Electrodes Reusable, Electrosurgical Electrodes Sterile Single use, Non Stick Bipolar Forceps Reusable, Bipolar Artery Sealer Reusable, Bipolar Scissor Reusable

Where the above scope includes class III medical device(s), a valid EC Design Examination Certificate according to Annex II (Section 4) is a mandatory requirement for each device in addition to this certificate to place that device on the market.

This certificate is valid from 25 March 2021 until 24 May 2024 and remains valid subject to satisfactory surveillance audits.
Issue 2. Certified since 20 August 2000

Certification is based on reports numbered PK/LHR 201127

Authorised by

Global Medical Devices Head of Notified Body

SGS Belgium NV, Notified Body 1639

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Tecno Instruments (Pvt) Ltd.

316-C Small Industrial
Estate, Sialkot-51340,
Pakistan.

02-02-2024

Confirmation Letter Reference: CLNB1639 – PK/LHR-201127

To whom it may concern,

Confirmation of receipt 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 devices.

This letter confirms that, SGS Belgium NV, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 1639 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

Legal Manufacturer:

Tecno Instruments (Pvt) Ltd.
316-C Small Industrial Estate,
Sialkot-51340, Pakistan
SRN Number: TBD

EU Authorized Representative:

OBELIS S.A
Bd. General Wahis, 53,
1030 Brussels, Belgium
SRN Number: BE-AR-000000106

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below . Table 1 identifies the devices 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 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; 02-10-2023.
- The certificates expired after 26th May 2021 by course of time and were valid at the date of their expiry neither having been suspended nor withdrawn.

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:

- 26th May 2026 for Class III custom-made implantable devices
- 31st 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)
- 31st December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31st 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 SGS Belgium NV 1639,



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Global Medical Device Certification Manager
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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	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
Bipolar Forceps sterile Single use w/wo cable, Monopolar Forceps Sterile Single use w/wo cable (8964001338410-EBF-EMFKK)	Class IIb	N/A	Certificate #PK19/818842627 NB1639
Finger Switch Pencil sterile single use, Electrosurgical Electrodes Sterile Single use (8964000207150-ESP-ETDPC)	Class IIb	N/A	Certificate #PK19/818842627 NB1639
Bipolar Forceps Reusable, Monopolar Forceps / Diathermy Inst Reusable, Non Stick Bipolar Forceps Reusable (8964000208310-EBF-EMFBX)	Class IIb	N/A	Certificate #PK19/818842627 NB1639

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
Device 1	N/A	N/A	N/A
Device 2	N/A	N/A	N/A
Device 3	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/02/02	Version 1	Initial issue

SGS NB1639 - Confirmation letter Regulation (EU) 2023/607