EU DECLARATION OF CONFORMITY

We,
TECNO INSTRUMENTS (PVT) LTD.

316-C, S.I.E., Sialkot - Pakistan

Hereby under our sole responsibility declares that below mentioned medical device(s) manufactured by us have been classified according to the classification rules stated in the Chapter III of Annex –VIII and conform to the General Safety and Performance Requirements as laid out in the Annex-I of the EU MDR 2017/745 as amended by 2020/561 and the CE marking may be affixed.

Device(s) Name:
Gynecological Instruments, Non-Sterile and Reusable

Device(s) Classification:
Class I according to Rule 5 of Chapter III in Annex-VIII, EU MDR 2017/745.

Conformity Assessment procedure:
Annex II, Annex III, Article 19 and Annex IV.

Single Registration Number (SRN):
PK-MF-000046748

Basic Unique Device(s) Identification (UDI-DI):
8964003293130-SPU-RETAH

European Medical Device(s) Nomenclature (EMDN):

EMDN Code	EMDN Description
U0899	Gynecological Devices - Other

Product List:

Sr. #	GMDN Code(s)	Product(s) name	Classification Rationale as per EU MDR 2017/745	Risk Class	Product Code / Catalogue #
1		Gynecological Devices - Other	Rule 5 of Chapter III in Annex-VIII, (EU) 2017/745	I	Appendix L

Catalog No.	Description	Size
130-109	Cusco	Medium

Intended Purpose(s):
Instruments are reusable, manual instruments designed for use in LEEP procedures such as General pelvic exam—visualization of the cervix or vagina. This is a reusable device.

Reference Regulation(s) / Standard(s) / Guidance Document(s) / Common Specification(s) (CS):
To which this declaration related is in conformity with the following standard(s) or other normative document(s).

Description	Standards/Regulation/CS
Medical Devices - Quality management systems Requirements for regulatory purposes	EN ISO 13485:2016 / A11-2021
General Criteria for Supplier's Declaration of Conformity	EN 45014:1998
Conformity assessment – Supplier's declaration of conformity	EN ISO/IEC 17050-1:2010
Application of Risk Management to Medical Devices	ISO 14971: 2019/A11:2021
Symbols used to express information supplied for a Medical Devices	ISO 15223-1:2021
Information to be supplied by the manufacturer of Medical Devices	ISO 20417:2021
Biological Evaluation of Medical Devices	EN ISO 10993-1:2020
Biological Evaluation of Medical Devices	ISO 10993-18:2020
Surgical Instruments – Specific Materials	EN ISO 7153-1:2016
Guidance on a Medical devices vigilance system	MEDDEV 2.12/1 rev.08
Processing of health care products	EN ISO 17664-1:2021
Sterilization of Health care products – Moist Heat	ISO 17665-1:2006

We have prepared and maintained technical documentation for each device(s) as required by Annex II &III of EU MDR 2017/745 as amended by 2020/561. The records are maintained for 10 years.

We have designated an EU Authorized Representative (EUAR):

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Notified Body Details: Not Applicable

Signed for and on behalf of: TECNO INSTRUMENTS (PVT) LTD.

Name: Haseeb Bhatti

Designation: Marketing Director

Place of Issue: 316-C, S.I.E., Sialkot - Pakistan

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