SU. INSTRUMENTS (PRIVATE) LIMITED

EC DECLARATION OF CONFORMITY

Date of Issuance: January 10, 2023 ***Valid till: January 09, 2027***

SU Instruments (PVT) Ltd.
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Sialkot 51310, Pakistan.
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Is registered with EUDAMED with SRN number **PK-MF-000035607,**
and competent authority **"DE/CA73 - Landesamt für Gesundheit und Soziales Berlin, Germany"**
Hereby declares that EC Representative had been appointed as follow for Medical Devices (Class I-Reusable)

YELLOW'S MEDICAL INSTRUMENTS GMBH
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Germany
Tel: +49-30 234 58 995
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We hereby declare that EC Declaration of Conformity is issued under the sole responsibility of the SU Instruments as per Article 19 and Annex IV and tends to meet the essential requirements as per Annex IV under Regulation (EU) 2017/745 (MDR 2017/745 for CE). Medical Devices attached in Annex A are in conformity with MDR 2017/745 and relevant harmonized standards and the relevant parts of applicable standards of Official Journal of the European Union, are applied where applicable and presumed to be in conformity with the requirements of **"Risk Class I"** of the device in accordance with rules set out in Annex VIII covered by those standards of parts thereof.

The Products manufactured are provided in Annex A of this EC Declaration of Conformity. The products declared in Annex A are in compliance to applicable standards and or are harmonized by EU Medical Devices Regulation 2017/745 and DE/CA73 - Landesamt für Gesundheit und Soziales Berlin, Germany. The traceability of the device covered by the EU Declaration of Conformity are in compliance where appropriated (Quality Management System and UDI) protocols, as well as its intended purpose.

We also declare; Products mentioned in Annex A of this declaration are in conformity with applicable general safety and performance requirements given in Annex I of MDR 2017/745 under the conditions of the intended us of the device. Documents will be presented upon request by DE/CA73 - Landesamt für Gesundheit und Soziales Berlin, Germany, the indicated therein SU Instruments will provided that technical documentation in its entirety and summary thereof.

The products manufactured are Reusable-Class I (Non-Sterilzed), low risk products in line with Annex VIII;

The products referred to Annex A are developed with due care in lieu of technical documentation referred to in Annex II and III of MDR 2017/745 and harmonized standards given in Annex B of this declaration.

To keep the technical documentation, the EU declaration of conformity and relevant certificates, including any amendments and supplements, issued in accordance with the article 56, available for the DE/CA73 - Landesamt für Gesundheit und Soziales Berlin, Germany for period of at least 10 years after the last device covered by the EU declaration of conformity has been placed on the market.

The Basic UDI-DI as referred to in Part C of Annex VI had been established in reference to the products in Annex A as per information to be submitted upon the registration of Devices and Economic Operators in accordance with article 28, 29 and 31.

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Annex A

Products List

Declares that products list has been classified as Medical Devices (Class I-Reusable) inclusive of mentioned products variant s/s in conformity with the essential requirements, provisions of Medical Devices Regulation 2017/745 and DE/CA73 - Landesamt für Gesundheit und Soziales Berlin, Germany has been appointed as EC Representative for following products.

Sr. No.	Product Group	Risk Class	PRODUCTS INFORMATIONN	PRODUCTS CODE (SUI)	PRODUCTS CODE (CUSOMER)	BASIC UDI-DI
1	Scissors	Class I	Surgical Scissors cvd.b/b16cm	SUBBC4155	SA-103-16	4055447002427
2	Scissors	Class I	Surgical Scissors cvd. b/b14cm	SUBBC4144	SA-103-14	4055447002717
3	Scissors	Class I	Surgical Scissors cvd. s/s16cm	SUBBC4266	SA-101-16	4055447002724
4	Scissors	Class I	Surgical Scissors cvd. s/s14cm	SUBBC4244	SA-101-14	4055447002731
5	Scissors	Class I	Surgical Scissors str. s/s 14cm	SUBBC3444	SA-100-14	4055447001963
6	Scissors	Class I	Surgical Scissors str. s/s 16cm	SUBBC3466	SA-100-16	4055447001970
7	Scissors	Class I	Surgical Scissors str. s/b 14cm	SUBBC3244	SA-104-14	4055447001376
8	Scissors	Class I	Surgical Scissors str. s/b 16cm	SUBBC3266	SA-104-16	4055447001956
9	Scissors	Class I	Surgical Scissors str. b/b 14cm	SUBBC3144	SA-102-14	4055447001918
10	Scissors	Class I	Surgical Scissors str. b/b 16cm	SUBBC3166	SA-102-16	4055447001925
11	Forceps	Class I	Dissecting Forceps 14.5cm	SUBBD0277	PI-524-14	4055447001512
12	Forceps	Class I	Dissecting Forceps 14.5cm	SUBBD1144	PI-522-14	4055447001437
13	Forceps	Class I	Dissecting Forceps 16cm	SUBBD0499	PI-501-16	4055447002748
14	Forceps	Class I	Tissue Forceps 14cm	SUBBD5577	PI-525-14	4055447001796
15	Forceps	Class I	Tissue Forceps 16 cm	SUBBD5599	PI-525-16	4055447002410
16	Forceps	Class I	Pean Forceps 14cm	SUBBH4244	KA-100-14	4055447001789
17	Forceps	Class I	Rochester Pean Forceps 16cm	SUBBH4422	KA-100-16	4055447002755
18	Forceps	Class I	Hemostatic Forceps Kocher 14cm	SUBBH6144	KA-102-14	4055447002120
19	Forceps	Class I	Kocher-Oschner Forceps 16cm	SUBBH6422	KA-102-16	4055447002762
20	Needle Holders	Class I	Needle Holder Mathieu	SUBBM3600	NA-100-14	4055447002595
21	Needle Holders	Class I	Needle Holder May-Hegar 15 cm	SUBBM2355	NA-101-14	4055447002779
22	Forceps	Class I	Cather Introducing forceps Magill 15cm	SUAAN3799	MA-402-15	4055447002151
23	Forceps	Class I	Cather Introducing forceps Magill 20cm	SUAAN3800	MA-402-20	4055447002168
24	Forceps	Class I	Cather Introducing forceps Magill 25cm	SUAAN3811	MA-402-25	4055447002175
25	Mallets	Class I	Diagnostic Hammer Buck	SUBBH400-RE	BH-400-19	4055447001871
26	Scissors	Class I	Lister Bandage Scissors 14 cm	SUBBC8611	SA-171-14	4055447001390
27	Scissors	Class I	Lister Bandage Scissors 16 cm	SUBBC4644	SA-171-16	4055447001406
28	Scissors	Class I	Lister Bandage Scissors 18 cm	SUBBC8622	SA-171-18	4055447001413
29	Scissors	Class I	Lister Bandage Scissors 20 cm	SUBBC8633	SA-171-20	4055447002786

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Annex B

The products mentioned in Annex A of this declaration are hereby declared in conformity with applicable harmonized standards mentioned below:

Standards	Description
Medical devices-Application of risk management to medical devices	ISO 14971
Medical Device Regulation (MDR)	Regulation (EU) 2017/745
Medical Devices quality management systems-Requirements for regulatory Purpose.	EN ISO 13485: 2016
Biological evaluation of medical devices-Part 1: Evaluation and testing	ISO 10993-1
Biological evaluation of medical devices-Part 2: Animal welfare requirements	ISO 10993-2
Biological evaluation of medical devices-Part 3: Test for genotoxity, carcinogenicity and reproductive toxicity	ISO 10993-3
Medical Devices-- symbols to be used with medical device labels, labeling, and information to be supplied – Part2: Symbols	ISO 15223-22:2010
Graphical Symbols for use in the labeling of medical devices	ISO 15223-1
Guide line for authorized representative	MEDDEV 2.5./10
Medical Devices classification	MEDDEV 2.4/1
Evaluation of clinical data-guide for manufacturer and notified bodies	MEDDEV 2.7.1 Appendix-1
Medical device vigilance system	MEDDEV 2.12.1
Standard specification for stainless steel billet, bar, and wire for Surgical Instruments	ASTM-F899
Surgical Instruments—Metallic Materials—Part 1: Stainless Steel	ISO 7153-1
Sterilization of Health care products	ISO 17665-1
Competent Authority (DE/CA73 - Landesamt für Gesundheit und Soziales Berlin)	

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