EC DECLARATION OF CONFORMITY

DOC-01-02
January 05, 2021

We,
Concise Enterprises,
Ahmed Din Estate. Noul More, Roras Road, Sialkot, 51310, Pakistan.
Declare under our sole responsibility that the product(s)

Surgical Forceps (Sterile, Non Sterile, Single Use)

Certificate	Certificate No.	Date of Issue	Date of Expiry
MDD 93/42/EEC	PK21/818842665	07 May 2021	Until 24 May 2024
EN 13485:2016	PK21/818842655	25 January 2021	Until 25 January 2024

As per Attached Article List as Annex-A Rev-0 TF-01

To which This declaration relates is in conformity with the following standard(s) or other normative standards(s)

Standards	Description
ISO 9001:2015	Quality Management Systems
EN ISO 13485:2016	Medical Devices-Quality Management Systems-Requirements for Regulatory Purpose
EN 1041:2008+A1:2013	Information supplied by the manufacturer of medical device
EN ISO 14971:2019	Medical Devices-Application of Risk Management to Medical Devices
ISO 11135:2014	Sterilization of health-care products — Ethylene oxide — Requirements for the development, validation and routine control of a sterilization process for medical devices
EN ISO 17664-2017	Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices
ISO 11607-1:2019	Packaging for terminally sterilized medical devices — Part 1: Requirements for materials, sterile barrier systems and packaging systems
ISO 11607-2:2019	Packaging for terminally sterilized medical devices — Part 2: Validation requirements for forming, sealing and assembly processes
ISO 11737-1:2018	Sterilization of health care products — Microbiological methods — Part 1: Determination of a population of microorganisms on products
ISO 11737-2:2019	Sterilization of health care products — Microbiological methods — Part 2: Tests of sterility performed in the definition, validation and maintenance of a sterilization process
ISO 15223-1:2016	Graphical Symbols for Use in the Labeling of Medical Devices

MDD 93/42/EEC Annex 1 MDD 93/42/EEC Annex V	Basic Requirements annex I EC Declaration of Conformity (Production Quality Assurance)
EN ISO 10993-1:2018	Biological Evaluation of Surgical Instruments
ISO 10993-5	Biological Evaluation of medical devices – Part 5 : Tests for in vitro Cytotoxicity
ISO 10993-10	Biological Evaluation of medical devices – Part 10 : Tests for irritation and skin sensitisation
EN ISO 7153-1:2016 ASTM F-899-12	Surgical Instruments – Metallic Materials – Part 1: Stainless Steel Standard Specification for Wrought Stainless Steels for Surgical Instruments

Following all the provisions of Council Directive 93/42/EEC updated directive 2007/47/EEC, Conformity Route Adopted Is according To Annexure V (Production Quality Assurance) and as per annexure IX under Rule 6 the classification of the devise is “Class IIa”.

This medical device is under the Supervision of notified body

SGS Belgium NV, Notified body (1639)
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EC REP

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Director Q.A

Place: Sialkot-Pakistan
Date: 05.01.2021