

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 |

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|-----------------------|---|
| MDD 93/42/EEC Annex I | Basic Requirements annex I |
| MDD 93/42/EEC Annex V | 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 | Surgical Instruments – Metallic Materials – Part 1: Stainless Steel |
| ASTM F-899-12 | 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)
SGS House Noorderlaan 87
2030 Antwerp, Belgium



CMC MEDICAL DEVICES & DRUGS, S.L.

C/ Horacio Lengo n18

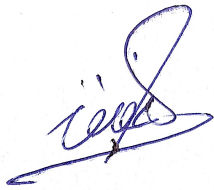
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Director Q.A

Place: Sialkot-Pakistan

Date: 05.01.2021

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|  |  |  |  | Meezan Bank Ltd 338-Kashmir Road, Sialkot 51310 – Pakistan | Export Registration No. W / 105413 Import Registration No. |
|  |  | Habib Bank Ltd Commercial Center, Paris Road, Sialkot 51310, Pakistan | Export Registration No. W / 105413 | | |