# EU DECLARATION OF CONFORMITY

We,

**Falcon Surgical Co. (Pvt) Ltd.** **(SRN: PK-MF-000018125)**

Wazirabad Road, Village Golophala, Sialkot-51310, Pakistan.

Hereby under sole responsibility declares that below mentioned medical devices are 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 Name:

Filling Instruments (Non-sterile, non-active, non-measuring, reusable)

## Device Classification:

Class I according to Rules 5, 1st indent set out in Chapter III of Annex-VIII, EU MDR 2017/745

## Conformity Assessment procedure:

Annex II, Annex III, Article 19 and Annex IV

## EMDN:

|  |  |
| --- | --- |
| **Code** | **Description** |
| Q01010101 | DENTAL CONVERSATION AMALGAMS |

## Basic Unique Device Identification (UDI-DI):

++G120FillingInstrumentRP

## Product List:

| **Sr. #** | **GMDN Code(s)** | **Product(s) name** | **Product Code / Catalogue #** |
| --- | --- | --- | --- |
|  | 35696 | Dental amalgam carrier | Appendix L |

***Note:***

*Refer to the respective Summary of Technical Documentation (STED), for the product’s photograph.*

## Intended Purpose(s):

A hand-held dental instrument specially designed to collect, transport and deposit amalgam in its plastic state into prepared cavities. This is a reusable device. For specific product please see (Appendix L).

## 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 |
| Medical Device Regulation (EU) of the European Parliament and of the Council | EU MDR 2017/745 as amended by 2020/561 |
| Guidance notes for manufacturers of class I medical devices | MDCG 2019-15 rev.1 |
| Conformity assessment – Supplier’s declaration of conformity – Part 1: General requirements | EN ISO/IEC 17050-1:2010 |
| Medical devices-Application of risk management to medical Devices | EN ISO 14971:2019 + A11:2021 |
| Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied part-1 –General requirement | EN ISO 15223-1:2021-07 |
| Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied – Part 2: Symbol development, selection and validation | EN ISO 15223-2:2010 |
| Medical devices — Information to be supplied by the manufacturer | EN ISO 20417:2021 |
| Biological evaluation of medical devices, part 1: evaluation and testing within a risk management process | EN ISO 10993-1:2020 |
| Biological evaluation of medical devices, part 18: chemical characterization of medical device materials within a risk management process | EN ISO 10993-18:2020 |
| Standard Specification for Wrought Stainless Steel for Surgical Instruments | ASTM F899-20 |
| Surgical Instruments – Metallic Materials – Part 1: Stainless Steel | EN ISO 7153-1:2016 |
| Surgical and Dental Hand Instruments – Determination of resistance against autoclaving, corrosion and thermal exposure | EN ISO 13402:2000 |
| Standard Test Method for Corrosion of Surgical Instruments | ASTM F1089-18 |
| Metallic materials – Rockwell hardness test – Part 1: Test method | EN ISO 6508-1:2016 |
| Clinical evaluation – guide for manufacturer and notified bodies | MEDDEV 2.7/1 Rev.4 |
| Guidance on clinical evaluation – Equivalence | MDCG 2020-5 |
| Guidance on sufficient clinical evidence for legacy devices | MDCG 2020-6 |
| Post-marketing surveillance (PMS) Recommendation | NB-Med 2\_12-1\_rev11 |
| Guidance on a Medical devices vigilance system | MEDDEV 2.12/1 rev.08 |
| Sterilization of health care products - Moist heat - Part 1: Requirements for the development, validation and routine control of a sterilization process for medical devices | EN ISO 17665-1:2006 |
| Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices - Part 1: Critical and semi-critical medical devices | EN ISO 17664-1:2021 |
| Dentistry - Medical devices for dentistry - Instruments | EN 1639:2009 |
| Dentistry – Materials for dental instruments – part 1: Stainless Steel | EN ISO 21850-1:2020 |

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.

## EU AUTHORIZED REPRESENTATIVE (EUAR):

**CMC MEDICAL DEVICES & DRUGS, S.L** **(SRN: ES-AR-000000293)**

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## Notified Body Details: *Not applicable*

**Signed for and on behalf of: Falcon Surgical Co. (Pvt) Ltd.**

|  |  |
| --- | --- |
| **Signature:** |  |
| **Name:** | **Muhammad Usman** |
| **Designation:** | **PRRC** |
| **Place of Issue:** | **Wazirabad Road, Village Golophala, Sialkot-51310, Pakistan.** |
| **Date of Issue:** | **21-02-2023** |