EU DECLARATION OF CONFORMITY

We,

Sehar Batool International (SRN:PK-MF-000025043)
S.I.E., Fateh garh, Near Umer Town, 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:
Emesis Bowl (Non-Sterile and Single Use)

Device(s) Classification:
Class I according to Rule 5, 1nd indent set out of Chapter III in Annex-VIII, EU MDR 2017/745

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

European Medical Device(s) Nomenclature (EMDN):

EMDN Code	EMDN Description
V0402	CLINICAL USE TRAYS AND BOWLS

Basic Unique Device(s) Identification (UDI-DI):
896110383EMESISBOWLXX

Product List:

Sr. #	GMDN Code(s)	Product(s) name	Product Code / Catalogue #
1.	42871	Emesis bowl, single-use	Appendix L

Note:
Refer to the respective Summary of Technical Documentation (STD), for the product's photograph.

Intended Purpose(s):
A device designed as a receptacle for vomit or oral secretions, typically from an immobile patient (e.g., one confined to bed, chair, or wheelchair). It is typically shallow and kidney-shaped, and therefore commonly known as a kidney bowl or basin. The device is also commonly used to hold and transport medical/surgical materials or instruments for a procedure. This is a single-use device. For specific use please see the (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
Conformity Assessment — Supplier's declaration of conformity — Part 2: Supporting documentation	EN ISO/IEC 17050-2:2004
Conformity assessment – Supplier's declaration of conformity – Part 1: General requirements	EN ISO/IEC 17050-1:2010

Description	Standards/Regulation/CS
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
Clinical evaluation – a guide for the 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 Ethylene oxide Requirements for the development, validation and routine control of a sterilization process for medical devices	ISO 11135:2014
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
Medical devices - Part 1: Application of usability engineering to medical devices	IEC 62366 –1: 2015 + A1:2020

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):
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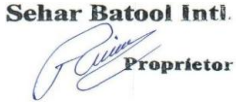
Notified Body Details: *Not applicable*

Signed for and on behalf of: Sehar Batool International.

Signature:	
Name:	**Amir Shahzad**
Designation:	**CEO**
Place of Issue:	**S.I.E., Fateh garh, Near Umer Town, Sialkot, Pakistan**
Date of Issue:	**04-11-2023**

Appendix L

REF #	Description (en)	Bezeichnung (de)
GS129414B	Kidney dish 250 x 130 x 30 mm non-sterile	Nierenschale 250 x 130 x 30 mm unsteril
GS129413B	Kidney dish 150 x 70 x 30 mm non-sterile	Nierenschale 150 x 70 x 30 mm unsteril