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:
Nail clippers (Non-Sterile and Single Use)

Device(s) Classification:
Class I according to Rule 1 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
L031399	Forceps, general surgery - others

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

Product List:

Sr. #	GMDN Code(s)	Product(s) name	Product Code / Catalogue #
1.	64032	Nail clippers, single-use	Appendix L

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

Intended Purpose(s):
A hand-held device designed specifically for trimming the nails of a patient. Also known as a nail cutter, it is a robust instrument comprised of two hinged cutting blades that are conjoined at the handle end of the device. The blades are sprung to hold them apart when not activated; when activated, the two blades are pressed together in a chopping motion to bite off (clip) the nail that has been positioned between them. It is not a pair of nail scissors. 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

Description	Standards/Regulation/CS
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
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):
CMC MEDICAL DEVICES & DRUGS, S.L (SRN:ES-AR-000000293)
C/ Horacio Lengo n18
C. P 29006
Málaga-Spain
Phone: +34 951 214 054
Email: info@cmcmedicaldevices.com

Notified Body Details: *Not applicable*

Signed for and on behalf of: Sehar Batool International.

Signature:	Sehar Batool Intl. Proprietor
Name:	**Amir Shahzad**
Designation:	**CEO**
Place of Issue:	**S.I.E., Fateh garh, Near Umer Town, Sialkot, Pakistan**
Date of Issue:	**27-11-2023**

Appendix L

REF #	Description (de)	Bezeichnung (en)
1415	PEDICE Eckenzange 10,5 cm spitze Schneide, unsteril	PEDICE corner forceps 10.5 cm pointed cutting edge, non-sterile
1416	PEDICE Eckenzange 11,5 cm lilienförmige Schneide, unsteril	PEDICE corner forceps 11.5 cm lily-shaped cutting edge, non-sterile
1418	PEDICE Nagelzange 13cm schlanke Schneide, unsteril	PEDICE nail forceps 13 cm slim cutting edge, non-sterile
1424	PEDICE Nagelzange 11,5cm mit Pufferfeder , unsteril	PEDICE nail forceps 11.5 cm with buffer spring, non-sterile
1426	PEDICE Nagel-/Eckenzange 13 cm mit gekappten Kanten, unsteril	PEDICE Nail/Corner Forceps 13 cm with capped edges, non-sterile
1427	PEDICE Eckenzange 11 cm mit gekappten Kanten, unsteril	PEDICE Corner Forceps 11 cm with capped edges, non-sterile
1428	PEDICE Eckenzange 13 cm gebogene Spitze , unsteril	PEDICE Corner Forceps 13 cm curved tip, non-sterile
1430	PEDICE Eckenzange 13 cm mit schmaler, langer Spitze, unsteril	PEDICE Corner Forceps 13 cm with narrow, long tip, non-sterile
1431	PEDICE Eckenzange 11,5 cm mit schmaler, langer Spitze, unsteril	PEDICE corner forceps 11.5 cm with narrow, long tip, non-sterile
1454	PEDICE Eckenzange DS DiabeticSafe 11cm , unsteril	PEDICE corner forceps DS DiabeticSafe 11 cm, non-sterile
1457	PEDICE Nagel- & Eckenzange DS DiabeticSafe 11,5 cm, unsteril	PEDICE Nail & Corner Nippers DS DiabeticSafe 11.5 cm, non-sterile
1458	PEDICE Nagelzange DS DiabeticSafe 13,5cm , unsteril	PEDICE Nail Nippers DS DiabeticSafe 13.5 cm, non-sterile
1486	PEDICE Nagelzange 15,5 cm m. Übersetzung , unsteril	PEDICE Nail Forceps 15.5 cm with transmission, non-sterile
1489	PEDICE Kopf-/Eckenzange 14 cm mit langer Schneide, unsteril	PEDICE Head/Corner Forceps 14 cm with long cutting edge, non-sterile
1493	PEDICE Short Cut MINI Nagelzange, 11 cm gerade, unsteril	PEDICE Short Cut MINI Nail Forceps, 11 cm straight, non-sterile
1494	PEDICE Short Cut Nagelzange, 12 cm , unsteril	PEDICE Short Cut Nail Forceps, 12 cm, non-sterile