Durrani & Co.

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Tel: 92 52 3259901-4
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EC DECLARATION OF CONFORMITY

We,

Durrani & Co.
Naul,Wazirabad Road, Sialkot-51310-Pakistan

Hereby under sole responsibility declares that below mentioned medical devices manufactured by us have been classified according to the classification rules stated in the Annex – IX and conform to the ESSENTIAL REQURIEMENT as laid out in MDD 93/42/EEC in Annex-I and change of classification will be updated till 31-Dec-2028 according to the EU MDR 2017/745 transition timeline as amended by 2020/561 and the CE marking may be affixed.

Device Name: Annex 1

Intended Purpose:
A hand-held manual surgical instrument designed to cut/dissect a variety of tissues during open surgery and having no dedication to a specific anatomy or clinical use; it might in addition be intended for cutting materials associated with surgery

Device Classification: Class: I Rule: 6 Indent: 2

Single Registration Number (SRN): PK-MF-000016079

Product List: Annex 1

Sr. #	Product Code / Catalogue #	Product name
1	02-014-140	Operating Scissors / Surgical Scissors, Sharp/Sharp, Straight, 14 cm

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

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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)

Sr.	Description	Standards/Regulation/CS
1	Medical devices – Quality management systems-Requirements for regulatory purposes.	EN ISO 13485:2016+AC:2018
2	Medical Device Regulation (EU) of the European Parliament and of the Council	EU MDR 2017/745 as amended by 2020/561
3	Guidance notes for manufacturers of class I medical devices	MDCG 2019-15 rev.1
4	Conformity assessment – Supplier's declaration of conformity – Part 1: General requirements	EN ISO/IEC 17050-1:2010
5	Medical devices-Application of risk management to medical Devices	EN ISO 14971:2019
6	Medical Devices – Symbols to be used with medical device labels, labeling and information to be supplied part-1 –general requirement	EN ISO 15223-1:2016
7	Medical devices – Symbols to be used with medical device labels, labeling, and information to be supplied – Part 2: Symbol development, selection and validation	ISO 15223-2:2010
8	Biological Evaluation of medical Devices – Part 1: Evaluation and testing within a risk management process	EN ISO 10993-1:2020
9	Biological evaluation of medical devices – Part 5: Tests for in vitro cytotoxicity	EN ISO 10993-5:2009
10	Biological evaluation of medical devices – Part 10: Tests for irritation	EN ISO 10993-10:2013
11	Standard Specification for Wrought Stainless Steel for Surgical	ASTM F899-20
12	Surgical Instruments – Metallic Materials – Part 1: Stainless Steel	EN ISO 7153-1:2016
13	Surgical and Dental Hand Instruments – Determination of resistance	EN ISO 13402:2000
14	Standard Test Method for Corrosion of Surgical Instruments	ASTM F1089-18
15	Clinical evaluation – guide for manufacturer and notified bodies	MEDDEV 2.7/1 Rev.4
16	Guidance on clinical evaluation – Equivalence	MDCG 2020-5
17	Guidance on sufficient clinical evidence for legacy devices	MDCG 2020-6
18	Best Practices for Medical Device Post Market Surveillance	ISO/TR 20416:2020
19	Post-marketing surveillance (PMS) Recommendation	NB-Med 2_12-1_rev11
20	Guidance on a Medical devices vigilance system	MEDDEV 2.12/1 rev.08
21	Processing of health care products – Information to be provided by	EN ISO 17664:2017
22	Sterilization of Health care products – Moist Heat – Part 1:	EN ISO 17665-1:2006

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Sr.	Description	Standards/Regulation/CS	
23	Comprehensive guide to steam sterilization and sterility assurance in	ANSI / AAMI ST79:2017	
24	Medical devices – Part 1: Application of usability engineering to	EN 62366-1:2015/A1:2020	
25	Safety aspects — Guidelines for the inclusion in standards	ISO/IEC Guide 51:2014	
26	Guide to the development and inclusion of aspects of safety in	ISO/IEC GUIDE 63:2019	

EU AUTHORIZED REPRESENTATIVE (EUAR):

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C. P 29006
Málaga-Spain

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Email: info@cmcmedicaldevices.com

Signed for and on behalf of:

Name: Gohar Durrani
Designation: Head of Regulatory Compliance
Place of Issue: Naul, Wazirabad Road, Sialkot-51310-Pakistan
Date of Issue: 8-Apr-21

DURRANI & COMPANY NAUL WZD Road SIALKOT PAKISTAN

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