EU REP CERTIFICATE

MDR 2017/745
Annex VIII Medical Device Regulation (MDR) Class I
Annex IV Conformity Assessment Class
MDR 2017 / 745 ARTICLE 11
(Devices Class 1 reusable)
No. AMS/CE/2020/3072016DE
SRN DE-AR-000008078

Manufacturer: Suma Medical Devices
24-617 Potters Street, Dharowal,
Sialkot-51310, Pakistan
HAS GIVEN A MANDATE TO

EU-Representative: ANTEX MEDI SOLUTION
HANS BUNTE STRASSE 6
69123 HEIDELBERG GERMANY

TO ACT AS
EU REPRECENTATIVE FOR

Medical Device Products CLASS 1 REUSABLE LISTED IN ATTACHED ANNEX I

The certificate remains valid until the expiration agreement of EU REP, manufacturing conditions, the quality system or relevant legislation are changed. The validity is conditioned by positive results of periodic surveillance audits.

The product liability rests with the manufacturer in accordance with applicable directive and standard, after fulfilling of the relevant EU legislation requirements, the manufacturer shall affix relevant CE marking to all below mentioned models of the medical device. The product classes covered are in ATTACHED ANNEX I of PAGE 1-1.

Date of Initial Registration: 17-07-2020
Certificate Renewal: 17-07-2021
Certificate Valid Until: 16-07-2022

Authorized Signatory

ANTEX MEDI SOLUTION

CE

ANTEX MEDI SOLUTION
HANS BUNTE STRASSE 6
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EU REP CERTIFICATE

ANNEX I PAGE 1/1:

List of Medical devices under the scope of the agreement

SURGICAL & DENTAL INSTRUMENTS

Nail Cutter
Scissors
Forceps
Tweezers
Mouth Mirrors
Needle Holders
Ear Speculas
Excavators
Curretes
Nose Speculas
Scalpels
Scalpel Handles

Authorized Signatory

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