

KONFORMITÄTSERKLÄRUNG / DECLARATION OF CONFORMITY

Wir / We

Name und Adresse der Firma:

Name and address of manufacturer:

Lipuma

Liaquat Ali Shaheed Road,
 Saboland Chowk, Bonkan,
 Sialkot, 51310-Pakistan

SRN: Applied

Bevollmächtigter:

Authorized Representative:

Antex-Medi-Solution

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SRN: DE-AR00008078

erklären in eigener Verantwortung, dass die im beigefügten Anhang I aufgeführten und von Lipuma gelieferten Medizinprodukte den Bestimmungen der EG-Richtlinie 93/42/EWG und den Sicherheits- und Leistungsanforderungen gemäß Anhang I der EU MDR 2017/745 in der Fassung 2020/561 entsprechen und die CE-Kennzeichnung angebracht werden darf.

declare on our own responsibility that the medical devices listed in attached Annex I and supplied by Lipuma, meet up with the regulations of the EC Directive 93/42/EEC, and 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.

Name, Adresse und Kennnummer
 der Benannte(n) Stelle(n)
*Name, address and identification
 number of Notified body(ies):*

Wird innerhalb der Übergangsfrist kontaktiert/
Will be contacted within the transitional timeline.

Risikoklasse/ Risk class:

Klasse I Medizinprodukte/ *Class I Medical devices*

Konformitätsbewertungsverfahren
Conformity assessment procedure:

CE nach EG-Richtlinie 93/42/ EWG Anhang VII
CE according to EC-Guideline 93/42/ EWG Annex VII

Basis-/UDI-DI:

Wird innerhalb der Übergangszeit folgen/ *Will follow
 within transitional timeline / Not issued yet*

5 Years

Gültigkeitsdauer / Validity

Sialkot-Pakistan 17-05-2021



(Inhaber/owner)

Name und Funktion / *Name and position*

Ort und Ausstellungsdatum/ Place and Date of issue

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 Raheel Hayder Sherazi
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Referenzverordnung(en) / Norm(en) / Leitfaden(e) / Gemeinsame Spezifikation(en) (CS)

Reference Regulation(s) / Standard(s) / Guidance Document(s) / Common Specification(s) (CS):

auf die sich diese Erklärung bezieht, mit der/den folgenden Norm(en) oder einem anderen normativen Dokument(en) übereinstimmt.

To which this declaration related is in conformity with the following standard(s) or other normative document(s)

Es wurden keine gemeinsamen Spezifikationen angewendet.

No Common Specifications applied.

Beschreibung/ Description	Standards/Regulation/CS
Medical devices – Quality management systems-Requirements for regulatory purposes.	EN ISO 13485:2016
Medical Device Regulation (EU) of the European Parliament and of the Council	MDD 93/42/EWG EU and 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
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
Information supplied by the manufacturer of medical devices	EN 1041:2008+A1:2013
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
Dentistry — Evaluation of biocompatibility of medical devices used in dentistry	ISO 7405:2018
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 5: Tests for in vitro cytotoxicity	EN ISO 10993-5:2009
Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization	EN ISO 10993-10:2013
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
Dentistry – Materials for dental instruments – part 1: Stainless Steel	EN ISO 21850-1:2020
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
Best Practices for Medical Device Post Market Surveillance	ISO/TR 20416:2020
Post-marketing surveillance (PMS) Recommendation	NB-Med 2_12-1_rev11
Guidance on a Medical devices vigilance system	MEDDEV 2.12/1 rev.08
Processing of health care products – Information to be provided by the medical device manufacturer for the processing of medical devices	EN ISO 17664:2017
Sterilization of Health care products – Moist Heat – Part 1: Requirements for the development, validation and routine control of a sterilization process for the medical devices	EN ISO 17665-1:2006
Comprehensive guide to steam sterilization and sterility assurance in health care facilities	ANSI / AAMI ST79:2017
Medical devices – Part 1: Application of usability engineering to medical devices	EN 62366-1:2015/A1:2020
Safety aspects — Guidelines for the inclusion in standards	ISO/IEC Guide 51:2014
Guide to the development and inclusion of aspects of safety in International Standards for medical devices	ISO/IEC GUIDE 63:2019

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Annex I

Medizinprodukte/ Medical devices:

1. Name / name UMDNS/GMDN-Code/ Artikel Nr. (siehe unten)
Typ / type or model UMDNS/GMDN-Code/ article No.
2. Los-, Chargen-, Serien-Nr., Stückzahlen oder Gültigkeitsdauer (laufende Bestellnummer)
lot-, batch-, serial-number, numbers of items or duration of validity (running order number)

Artikel	UPN / UDI Gerätekennezeichen	Beschreibung CHIRURGISCHE UND ZAHNÄRZTLICHE INSTRUMENTE	Verordnung	Regel	Klassifizierung	Verwendungszweck
Article	UPN/UDI Device Identifier	Description SURGICAL & DENTAL INSTRUMENTS	Regulation	Rule	Classification	Intended Use
30206	G158302060	<u>Ruber Dam Clamps</u>	MDD - Directive 93/42	6	CLASS I	It particularly useful in securing and retracting tissue during excision of subcutaneous tumors such as cysts or lipomas.
30203	G158302030	<u>Root Elevators</u>	MDD - Directive 93/42	5	CLASS I	A surgical elevator is a tool used for scraping, elevating or dissecting bones or tissues.
30210	G158302100	<u>Forceps</u>	MDD - Directive 93/42	5	CLASS I	Their primary purpose is to grasp, retract, or stabilize tissue.
30211	G158302110	<u>Tooth Extracting Forcep</u>	MDD - Directive 93/42	5	CLASS I	Extraction forceps are used along with elevators to extract teeth
30207	G158302070	<u>Wax Knives</u>	MDD - Directive 93/42	6	CLASS I	Knives are used as a cutting instrument; has a pointed blade with a sharp edge and a handle.
30208	G158302080	<u>Scalpel Handles</u>	MDD - Directive 93/42	6	CLASS I	Scalpels or Scalpel Handles are intended to be use with surgical blades for tissue separation
30209	G158302090	<u>Needel Holders</u>	MDD - Directive 93/42	6	CLASS I	Needle holder, also called needle driver, is a surgical instrument, similar to a hemostat, used by doctors and surgeons to hold a suturing needle for closing wounds during suturing and surgical procedures. The parts of a simple needle holder are the jaws, the joint and the handles.

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30205	G158302050	<u>Ruber Dam Fcp & Pliers</u>	MDD - Directive 93/42	6	CLASS I	Surgical punches are used to simplify the collection of biopsy samples and the dissection or removal of tonsils. Though these two medical procedures are common, they are also delicate operations.
30205A	G158303100	<u>Ruber Dam Frame</u>	MDD - Directive 93/42	6	CLASS I	Dental rubber dam frames are used to hold rubber dams in place while they are being used to isolate the operative tooth or teeth
30214	G158302140	<u>Bone Rongeurs</u>	MDD - Directive 93/42	6	CLASS I	Rongeurs are used for gnawing holes in bones during surgery.
30204	G158302040	<u>Scaler</u>	MDD - Directive 93/42	5	CLASS I	Scaler is used to locate and remove unsightly stains, plaque and bacterial debris. This debris is located on and between the teeth, along the gum lines, on both the front and backside of the teeth and dentures.
3020401	G15830204010	Hemingway Spoon double ended, Fig No. 1 small	MDD - Directive 93/42	5	CLASS I	Hemingway spoon double ended with two, semi-sharp spoon -like tips designed to grasp and remove the soft tissue after the use of a tissue punch
3020402	G15830204020	Hemingway Spoon double ended, Fig No. 2 medium	MDD - Directive 93/42	5	CLASS I	Hemingway spoon double ended with two, semi-sharp spoon -like tips designed to grasp and remove the soft tissue after the use of a tissue punch
3020403	G15830204030	Hemingway Spoon double ended, Fig No. 3 big	MDD - Directive 93/42	5	CLASS I	Hemingway spoon double ended with two, semi-sharp spoon -like tips designed to grasp and remove the soft tissue after the use of a tissue punch

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3020407	G15830204070	Excavator small (hemisphere)	MDD - Directive 93/42	5	CLASS I	An excavator is an instrument used in dentistry for the fulfillment of cavities in the dentin and for the detection of caries and calculations , and has a right or left orientation
3020408	G15830204080	Excavator medium (hemisphere)	MDD - Directive 93/42	5	CLASS I	An excavator is an instrument used in dentistry for the fulfillment of cavities in the dentin and for the detection of caries and calculations , and has a right or left orientation
3020409	G15830204090	Excavator big (hemisphere)	MDD - Directive 93/42	5	CLASS I	An excavator is an instrument used in dentistry for the fulfillment of cavities in the dentin and for the detection of caries and calculations , and has a right or left orientation
3020410	G15830204100	Amalgam Instrument double End, Fig No. 1	MDD - Directive 93/42	5	CLASS I	Amalgam Instrument is the tool used by dentists to condense amalgam in the small and medium-size cavities of teeth
3020411	G15830204110	Amalgam Instrument double End, Fig No. 2	MDD - Directive 93/42	5	CLASS I	Amalgam Instrument is the tool used by dentists to condense amalgam in the small and medium-size cavities of teeth
3020412	G15830204120	Amalgam Instrument double End, Fig No. 3	MDD - Directive 93/42	5	CLASS I	Amalgam Instrument is the tool used by dentists to condense amalgam in the small and medium-size cavities of teeth

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3020413	G15830204130	Mall, Amalgam Instrument No. 1 small	MDD - Directive 93/42	5	CLASS I	Amalgam Instrument is the tool used by dentists to condense amalgam in the small and medium-size cavities of teeth
3020414	G15830204140	Mall, Amalgam Instrument No. 2 medium	MDD - Directive 93/42	5	CLASS I	Amalgam Instrument is the tool used by dentists to condense amalgam in the small and medium-size cavities of teeth
3020415	G15830204150	Mall, Amalgam Instrument No. 3 big	MDD - Directive 93/42	5	CLASS I	Amalgam Instrument is the tool used by dentists to condense amalgam in the small and medium-size cavities of teeth
3020416	G15830204160	Elevator n. Williger	MDD - Directive 93/42	5	CLASS I	elevator instruments are used to luxate teeth, and this technique imparts forces to tooth particles that sever the periodontal ligament around tooth roots inside the socket and expand alveolar bone around tooth particles
30202	G158302020	<u>Scissors</u>	MDD - Directive 93/42	6	CLASS I	Scissors are are used to cut soft tissue.
30212	G158302120	<u>Cartridge Syringes</u>	MDD - Directive 93/42	5	CLASS I	A dental syringe is a syringe used by dentists for the injection of an anesthetic. It consists of a breech-loading syringe fitted with a sealed cartridge containing anesthetic solution.
30215	G158302150	<u>Impression Trays</u>	MDD - Directive 93/42	5	CLASS I	Impressions trays are used in the dental surgery to produce accurate (varying degrees of accuracy) negative reproductions of the patients' teeth, surrounding tissues and dental arches.

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30201	G158302010	<u>Tweezer</u>	MDD - Directive 93/42	6	CLASS I	Tweezers are small tools used for picking up objects too small to be easily handled with the human fingers.
30213	G158302130	<u>Crown Removers</u>	MDD - Directive 93/42	5	CLASS I	Crown removers are instruments ment to remove the artificial crowns or fixed dentures from the oral cavity. The crown removers act like pneumatic hammers.

5 Years

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Gültigkeitsdauer / Validity

.....
(Inhaber/owner)
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