



Tel : 0092 52 3555682
Fax : 0092 52 3550718
E-mail: info@passauimpex.com
Website: www.passauimpex.com

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EU Declaration of Conformity

We,

Passau Impex

SRN-Nr.PK-MF-000032393

21-23, Nishtar Road, S.I.E. Sialkot, Pakistan.

With the Scope of

Manufacturer and Exporter of non-sterile, non-active, Reusable, Surgical, Dental, Orthodontic & Diagnostic Instruments

Herewith declare under our own responsibility, that all listed medical devices
Instruments of Risk-Class I, Class Ir

Classified according to Regulation MDR 2017/745 annex VIII chapter 1 into risk class I,
Class Ir

have been manufactured under consideration of following Regulation:

European Regulation 2017/745 (MDR) + Corrigendum I and II

Applied conformity assessment according Annex IV of MDR 2017/745.

The listed product meet the essential safety- and performance requirements of the European Regulation Annex I of Regulation (EU) 2017/745 and are therefore placed into market with CE

EU Authorized Representative

KB International

SRN-Nr. HU-AR-000034102

Budapest, Auróra utca, 13. al. 1, BUDAPEST, Hungary

We herewith declare and certify that the mentioned devices technical documentations meet the provisions of the Medical Device Regulation (EU) 2017/745 with the Annex II, III, IV. The products list is attached in Annex A of this declaration. We shall maintain these documentations for 10 years from the data of their production.



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Whereas our all products are manufactured under the guidelines of the following international standards:

<i>ISO 9001:2015</i>	<i>Quality Management System</i>
<i>EN ISO 13485:2016</i>	<i>Medical Devices Quality Management System</i>
<i>EN ISO 14971:2019</i>	<i>Medical Devices - Application of Risk Management to Medical Devices</i>
<i>ISO 7153-1:2016</i>	<i>Surgical Instruments Metallic Materials - Part-1: Stainless Steel</i>
<i>BS EN 1041:2008+A1:2013</i>	<i>Information Supplied by the Manufacturer with Medical Devices</i>
<i>BS EN ISO 15223-1:2016</i>	<i>Medical Devices, Symbol to be used with Medical Device Labels, Labeling and Information to be supplied</i>
<i>ISO 17664:2017</i>	<i>Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices</i>
<i>ASTM F899-12b</i>	<i>Standard Specification for Wrought Metals for Surgical Instruments</i>

PASSAU IMPEX


Managing Partner
PASSAU IMPEX
Sialkot, Pakistan
Date: 12-01-2024

Annex A

Registration No.: EAR/PK/7224

UMDNS	Product Name	Risk Class
13399	Cutters, Ring	Ir
13416	Rongeurs	Ir
13288	Rasps	Ir
13448	Saws	Ir
13454	Scalers	Ir
13480	Scissors	Ir
13481	Scissors, Bandage	Ir
13485	Scissors, Eye	Ir
13492	Scissors, Dissecting	Ir
13508	Scoops	Ir
13662	Specula, Ear	Ir
13663	Specula, Eye	Ir
13644	Sounds, Uterine	Ir
13645	Spatulas	Ir
13664	Specula, Nasal	Ir
13666	Specula, Vaginal	Ir
13707	Spreaders	Ir
13730	Sterilization Containers	I
13929	Syringes	Ir
14066	Tongue Depressors	I
14146	Trephines	Ir
14255	Tuning Forks	I
14257	Tweezers	Ir
14291	Urinals	I
15221	Forceps, Other	Ir
15573	Cutters	Ir
15561	Bowls	I
15586	Jars	I
15602	Specula, Ophthalmic	Ir
15609	Trays	I
15621	Microsurgical Instruments	Ir
15710	Extracing Forceps, Dental	Ir
15711	Punches, Dental, Rubber Dam	Ir
15712	Clamps, Dental, Rubber Dam	Ir
13416	Rongeurs	Ir
16179	Amalgam Carriers	Ir
16209	Forceps, Ophthalmic	Ir
16350	Trays, Impression, Dental	Ir
16357	Crown/Inlay Removers	Ir
16412	Burnishers	Ir
16426	Carvers, Dental Amalgam	Ir
16427	Carvers, Dental Wax	Ir
16482	Explorers	Ir
16651	Forceps, Rubber Dam Clamp	Ir
16664	Dental Hand Instruments,	Ir
16666	Dental Hand Instruments, Surgical	Ir
17954	Hand Drills, Surgical	Ir

UMDNS	Product Name	Risk Class
10172	Applicators	Ir
10199	Articulators	Ir
10339	Bedpans	I
10455	Cutters, Bone	Ir
10546	Calipers	Ir
10685	Catheters	Ir
10824	Chisels	Ir
10861	Clamps	Ir
10869	Clamps, Circumcision	Ir
11084	Curettes	Ir
11254	Dilators	Ir
11155	Rubber Dams, Dental	Ir
11160	Dental Hand Instruments, Wax Knives	Ir
11289	Dissecting Kits	Ir
11290	Dissectors	Ir
11504	Elevators	Ir
11774	Forceps,	Ir
11784	Forceps, Hemostatic	Ir
11788	Forceps, Obstetrical	Ir
11701	Files	Ir
11702	Files, Bone	Ir
11947	Hammers	Ir
11950	Hammers, Percussion	I
11895	Gouges	Ir
12028	Hooks	Ir
12143	Trays, Instrument	I
12235	Scalpel Handles	Ir
12239	Knives	Ir
12421	Mallets	Ir
12293	Laryngoscopes	Ir
12547	Mirrors	I
12549	Mirrors, Laryngeal	Ir
12726	Needle Holders	Ir
12815	Ophthalmoscopes	I
12844	Osteotomes	Ir
12849	Otoscopes	I
13041	Cutters, Pin and Wire	Ir
13117	Probes	Ir
13126	Proctoscopes	Ir
13228	Punches	Ir
13373	Retractors, all types	Ir
13375	Retractors, Abdominal	Ir