

Ref:PI-DOC-01/Rev.00/12-01-2024

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.*



PASSAU IMPEX

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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
M. Tabbal

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

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