



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

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.*



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

*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,<br>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<br>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         |