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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.



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

ISO 9001:2015 Quality Management System

EN ISO 13485:2016 Medical Devices Quality Management System

Medical Devices - Application of Risk Management to Medical EN ISO 14971:2019

**Devices** 

ISO 7153-1:2016 Surgical Instruments Metallic Materials - Part-1: Stainless

Steel

BS EN 1041:2008+A1:2013 Information Supplied by the Manufacturer with Medical

**Devices** 

BS EN ISO 15223-1:2016 Medical Devices, Symbol to be used with Medical Device

Labels, Labeling and Information to be supplied

ISO 17664:2017 Processing of health care products - Information to

be provided by the medical device manufacturer for

the processing of medical devices

ASTM F899-12b Standard Specification for Wrought Metals for

Surgical Instruments



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



## Annex A Registration No.: EAR/PK/7224

13399	UMDNS	Product Name	Risk Class
13416	13399	Cutters, Ring	
13288	13416		lr
13454   Scalers	13288		lr
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   13664   Sounds, Uterine   Ir   13645   Spatulas   Ir   13666   Specula, Nasal   Ir   13666   Specula, Vaginal   Ir   13707   Spreaders   Ir   13730   Sterilization Containers   Ir   13730   Sterilization Containers   Ir   14066   Tongue Depressors   Ir   14255   Tuning Forks   Ir   14257   Tweezers   Ir   14257   Tweezers   Ir   14291   Urinals   Ir   15561   Bowls   Ir   155602   Specula, Ophthalmic   Ir   15609   Trays   Ir   15609   Trays   Ir   15710   Extracing Forceps, Dental   Ir   15711   Punches, Dental, Rubber Dam   Ir   15712   Clamps, Dental, Rubber Dam   Ir   16357   Crown/Inlay Removers   Ir   16357   Crown/Inlay Removers   Ir   16426   Carvers, Dental Amalgam   Ir   16357   Crown/Inlay Removers   Ir   16426   Carvers, Dental Amalgam   Ir   16427   Carvers, Dental Amalgam   Ir   16427   Carvers, Dental Amalgam   Ir   16427   Carvers, Dental Amalgam   Ir   16664   Dental Hand Instruments, Ir   Ir   16666   I	13448	Saws	lr
13481   Scissors, Bandage	13454	Scalers	lr
13485	13480	Scissors	Ir
13485	13481	Scissors, Bandage	lr
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           14257         Tweezers         Ir           14255         Tuning Forks         I           14257         Tweezers         Ir           14251         Urinals         I           15221         Forceps, Other         Ir           15573         Cutters         Ir           15561         Bowls         I           15586         Jars         I           15602         Specula, Ophthalmic         Ir           15710	13485		lr
13508         Scoops         Ir           13662         Specula, Ear         Ir           13663         Specula, Eye         Ir           13644         Sounds, Uterine         Ir           13645         Spatulas         Ir           13664         Specula, Nasal         Ir           13665         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           14257         Tweezers         Ir           14291         Urinals         I           15221         Forceps, Other         Ir           15573         Cutters         Ir           15561         Bowls         I           15586         Jars         I           15609         Trays         I           15621         Microsurgical Instruments         Ir           15710         Ex	13492	Scissors, Dissecting	lr
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           14406         Trogue Depressors         I           14414         Trephines         Ir           14255         Tuning Forks         I           14257         Tweezers         Ir           14257         Tweezers         Ir           14257         Tweezers         Ir           14257         Tweezers         Ir           15573         Cutters         Ir           15561         Bowls         I           15562         Jars         I           15586         Jars         I           15602         Specula, Ophthalmic         Ir           15710         Extracing Forceps, Dental         Ir           15711	13508		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           14406         Trogue Depressors         I           14414         Trephines         Ir           14255         Tuning Forks         I           14257         Tweezers         Ir           14257         Tweezers         Ir           14257         Tweezers         Ir           14257         Tweezers         Ir           15573         Cutters         Ir           15561         Bowls         I           15562         Jars         I           15586         Jars         I           15602         Specula, Ophthalmic         Ir           15710         Extracing Forceps, Dental         Ir           15711	13662	Specula, Ear	lr
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           14257         Tweezers         Ir           14251         Urinals         I           15221         Forceps, Other         Ir           15573         Cutters         Ir           15561         Bowls         I           15586         Jars         I           15580         Jars         I           15602         Specula, Ophthalmic         Ir           15710         Extracing Forceps, Dental         Ir           15711         Punches, Dental, Rubber Dam         Ir           15712         Clamps, Dental, Rubber Dam         Ir      <	13663	Specula, Eye	lr
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           14257         Tweezers         Ir           14291         Urinals         I           15221         Forceps, Other         Ir           15573         Cutters         Ir           15561         Bowls         I           15562         Jars         I           15561         Bowls         I           15586         Jars         I           15602         Specula, Ophthalmic         Ir           15710         Extracing Forceps, Dental         Ir           15711         Punches, Dental, Rubber Dam         Ir           15712         Clamps, Dental, Rubber Dam         Ir	13644	Sounds, Uterine	Ir
13664         Specula, Nasal         Ir           13666         Specula, Vaginal         Ir           13707         Spreaders         Ir           13730         Sterilization Containers         I           13929         Syringes         Ir           14066         Tongue Depressors         I           14406         Trephines         Ir           14406         Tongue Depressors         I           14267         Trephines         Ir           14267         Tweezers         Ir           14257         Tweezers         Ir           14291         Urinals         I           15221         Forceps, Other         Ir           15573         Cutters         Ir           15561         Bowls         I           15586         Jars         I           15602         Specula, Ophthalmic         Ir           15710         Extracing Forceps, Dental         Ir <t< td=""><td>13645</td><td>Spatulas</td><td>lr</td></t<>	13645	Spatulas	lr
13666         Specula, Vaginal         Ir           13707         Spreaders         Ir           13730         Sterilization Containers         I           13929         Syringes         Ir           14066         Tongue Depressors         I           14406         Trongue Depressors         I           14446         Trephines         Ir           14255         Tuning Forks         I           14257         Tweezers         Ir           14257         Tweezers         Ir           14291         Urinals         I           15221         Forceps, Other         Ir           15573         Cutters         Ir           15561         Bowls         I           15586         Jars         I           15580         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 </td <td>13664</td> <td>Specula, Nasal</td> <td>lr</td>	13664	Specula, Nasal	lr
13707         Spreaders         Ir           13730         Sterilization Containers         I           13929         Syringes         Ir           14066         Tongue Depressors         I           14146         Trephines         Ir           14255         Tuning Forks         I           14257         Tweezers         Ir           14257         Tweezers         Ir           14291         Urinals         I           15221         Forceps, Other         Ir           15573         Cutters         Ir           15561         Bowls         I           15586         Jars         I           15580         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           16179         Amalgam Carriers         Ir           16209         Forceps, Ophthalmic         Ir	13666		lr
13730         Sterilization Containers         I           13929         Syringes         Ir           14066         Tongue Depressors         I           14146         Trephines         Ir           14255         Tuning Forks         I           14257         Tweezers         Ir           14257         Tweezers         Ir           14291         Urinals         I           15221         Forceps, Other         Ir           15573         Cutters         Ir           15561         Bowls         I           15586         Jars         I           15580         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           16179         Amalgam Carriers         Ir           16209         Forceps, Ophthalmic         Ir           16350         Trays, Impression, Dental	13707	Spreaders	
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           15562         Bowls         I           15586         Jars         I           15602         Specula, Ophthalmic         Ir           15609         Trays         I           15609         Trays         I           15621         Microsurgical Instruments         Ir           15710         Extracing Forceps, Dental         Ir           15711         Punches, Dental, Rubber Dam         Ir           15712         Clamps, Dental, Rubber Dam         Ir           16179         Amalgam Carriers         Ir           16209         Forceps, Ophthalmic         Ir           16350         Trays, Impression, Dental         Ir           16357         Crown/Inlay Removers         Ir           16412         Burnishers	13730	Sterilization Containers	1
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           15580         Jars         I           15602         Specula, Ophthalmic         Ir           15609         Trays         I           15601         Microsurgical Instruments         Ir           15710         Extracing Forceps, Dental         Ir           15711         Punches, Dental, Rubber Dam         Ir           15712         Clamps, Dental, Rubber Dam         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	13929	Syringes	lr
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           15580         Jars         I           15580         Jars         I           15602         Specula, Ophthalmic         Ir           15609         Trays         I           15609         Trays         I           15621         Microsurgical Instruments         Ir           15710         Extracing Forceps, Dental         Ir           15711         Punches, Dental, Rubber Dam         Ir           15712         Clamps, Dental, Rubber Dam         Ir           16179         Amalgam Carriers         Ir           16209         Forceps, Ophthalmic         Ir           16350         Trays, Impression, Dental         Ir           16357         Crown/Inlay Removers         Ir           16412         Burnishers         Ir </td <td>14066</td> <td></td> <td>I</td>	14066		I
14255         Tuning Forks         I           14257         Tweezers         Ir           14291         Urinals         I           15221         Forceps, Other         Ir           15573         Cutters         Ir           15561         Bowls         I           15562         Bowls         I           15586         Jars         I           15602         Specula, Ophthalmic         Ir           15609         Trays         I           15609         Trays         I           15621         Microsurgical Instruments         Ir           15710         Extracing Forceps, Dental         Ir           15711         Punches, Dental, Rubber Dam         Ir           15712         Clamps, Dental, Rubber Dam         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<	14146		lr
14291         Urinals         I           15221         Forceps, Other         Ir           15573         Cutters         Ir           15561         Bowls         I           15586         Jars         I           155802         Specula, Ophthalmic         Ir           15609         Trays         I           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           16651         Forceps, Rubber Dam Clamp         Ir           16664	14255		ı
15221         Forceps, Other         Ir           15573         Cutters         Ir           15561         Bowls         I           15586         Jars         I           15580         Specula, Ophthalmic         Ir           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           16651         Forceps, Rubber Dam Clamp         Ir           16664         Dental Hand Instruments,         Ir	14257	Tweezers	lr
15573         Cutters         Ir           15561         Bowls         I           15586         Jars         I           15602         Specula, Ophthalmic         Ir           15609         Trays         I           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           16651         Forceps, Rubber Dam Clamp         Ir           16664         Dental Hand Instruments,         Ir           16666         Dental Hand Instruments,         Ir <td>14291</td> <td>Urinals</td> <td>1</td>	14291	Urinals	1
15573         Cutters         Ir           15561         Bowls         I           15586         Jars         I           15580         Specula, Ophthalmic         Ir           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           16651         Forceps, Rubber Dam Clamp         Ir           16664         Dental Hand Instruments,         Ir           16666         Dental Hand Instruments,         Ir			lr
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           16651         Forceps, Rubber Dam Clamp         Ir           16664         Dental Hand Instruments,         Ir           16666         Dental Hand Instruments,         Ir	15573		Ir
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,         Ir	15561	Bowls	1
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,         Ir           Surgical	15586	Jars	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,         Ir	15602	Specula, Ophthalmic	lr
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,         Ir           Surgical	15609	Trays	1
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,         Ir           Surgical	15621	Microsurgical Instruments	lr
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,         Ir           Surgical	15710	Extracing Forceps, Dental	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,         Ir           Surgical	15711	Punches, Dental, Rubber Dam	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,         Ir           Surgical	15712	Clamps, Dental, Rubber Dam	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,         Ir           Surgical         Ir			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,         Ir           Surgical         Ir	16179		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,         Ir           Surgical         Ir	16209	Forceps, Ophthalmic	lr
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,         Ir           Surgical	16350	Trays, Impression, Dental	lr
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, Ir Surgical	16357	Crown/Inlay Removers	Ir
16427 Carvers, Dental Wax Ir 16482 Explorers Ir 16651 Forceps, Rubber Dam Clamp Ir 16664 Dental Hand Instruments, Ir 16666 Dental Hand Instruments, Ir Surgical	16412		Ir
16427 Carvers, Dental Wax Ir 16482 Explorers Ir 16651 Forceps, Rubber Dam Clamp Ir 16664 Dental Hand Instruments, Ir 16666 Dental Hand Instruments, Ir Surgical	16426	Carvers, Dental Amalgam	lr
16651 Forceps, Rubber Dam Clamp Ir 16664 Dental Hand Instruments, Ir 16666 Dental Hand Instruments, Ir Surgical	16427	Carvers, Dental Wax	Ir
16651 Forceps, Rubber Dam Clamp Ir 16664 Dental Hand Instruments, Ir 16666 Dental Hand Instruments, Ir Surgical	16482		lr
16664 Dental Hand Instruments, Ir 16666 Dental Hand Instruments, Ir Surgical	16651		Ir
Surgical	16664	Dental Hand Instruments,	Ir
	16666	Dental Hand Instruments,	Ir
17954 Hand Drills, Surgical Ir			
	17954	Hand Drills, Surgical	lr

UMDNS	Product Name	Risk Class
10172	Applicators	lr
10199	Articulators	lr
10339	Bedpans	i
10455	Cutters, Bone	lr
10546	Calipers	lr
10685	Catheters	ir
10824	Chisels	lr
10861	Clamps	Ir
10869	Clamps, Circumcision	Ir
11084	Curettes	Ir
11254	Dilators	Ir
11155	Rubber Dams, Dental	Ir
11160	Dental Hand Instruments, Wax	lr
	Knives	
11289	Dissecting Kits	Ir
11290	Dissectors	Ir
11504	Elevators	lr
11774	Forceps,	Ir
11784	Forceps, Hemostatic	lr
11788	Forceps, Obstetrical	Ir
11701	Files	lr
11702	Files, Bone	Ir
11947	Hammers	lr
11950	Hammers, Percussion	I
11895	Gouges	lr
12028	Hooks	Ir
12143	Trays, Instrument	I
12235	Scalpel Handles	Ir
12239	Knives	lr
12421	Mallets	lr
12293	Laryngoscopes	lr
12547	Mirrors	1
12549	Mirrors, Laryngeal	Ir
12726	Needle Holders	Ir
12815	Ophthalmoscopes	I
12844	Osteotomes	Ir
12849	Otoscopes	1
13041	Cutters, Pin and Wire	Ir
13117	Probes	lr
13126	Proctoscopes	lr
13228	Punches	lr
13373	Retractors, all types	lr
13375	Retractors, Abdominal	lr