



Sehgal's Instruments

Manufactures & Exporters of Surgical, Dental, and Veterinary & Beauty care Instruments

DECLARATION OF CONFORMITY

Reference#: SIDOC 10-5-2021

Dated:10-5-2021

We hereby declare that;

Sehgal's Instruments

Ghummanst.PakkiKotliDaska Road Sialkot 51340 Pakistan

appointed EC Representative registered in EUDAMED as by SRN #SE-AR-000001625

IBC – Sweden

14564 Norsborg

Stockholm, Sweden

Email: eurep@ibcsweden.eu

Phone: +46 734442169

SRN: SE-AR-000001625

And is registered with Competent Authority “Swedish Medical Products Agency – Läkemedelsverket” with diary number **6.6.1-2021-38524** and for following products manufactured in accordance with CE Mark requirements;

Products: Re-useable Surgical Instruments fall in Class 1

Variant: Including variants given in Annex A of this declaration

We Sehgal's Instruments under sole responsibility declares that the below mentioned devices have been classified as class I reusable medical devices according to the classification rules stated in the Annex–IX and conform to the Essential Safety and Performance as laid out in the Annex– I of Council Directive 93/42/EEC for medical devices given in Annex A to this document meet the essential requirement of Directive No. 93/42/.

Each type of medical device to which the technical documentation complies with the applicable provisions of the essential principles and following mentioned harmonized standards.

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

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EN ISO/ISO 13485	MEDICALDEVICES-QUALITY MANAGEMENTSYSTEMS-REQUIREMENTS FORREGULATORYPURPOSES
EN ISO/ISO 14971	MEDICALDEVICES- APPLICATIONOFRISK MANAGEMENTTOMEDICALDEVICES
ISO 13485:2016	Medical Devices-Quality Management Systems-Requirements for Regulatory Purpose
93/42/EEC	Council Directive for Medical Devices,
ASTM-F899	Standard Specification for Stainless Steel Billet, Bar, and Wire for Surgical Instruments
ISO 7153-1	Surgical Instruments – Metallic Materials – Part 1: Stainless Steel

Authorised Signatory:

Sehgal's INSTRUMENTS

.....PARTNER

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Annex A

Reference	BRAND	PRODUCT NAME
7763	No Logo	DIAPASON C128 INOX
7777	No Logo	DIAPASON C256 INOX
36895	LABODERM	CISEAUX SPENCER COURBES 90MM INOX
7115	LABODERM	CISEAUX SPENCER COUPE FILS DROITS 90MM INOX
71490	LABODERM	CISEAUX LIGATURE SPENCER DROITS 110MM SUPCUT
71495	LABODERM	CISEAUX IRIDECTOMIE DROIT MOUSSE 115MM TUNGSTENET
71262	LABODERM	CISEAUX IRIDECTOMIE DROIT EVIDES PTS 105MM INOX
71267	LABODERM	CISEAUX IRIDECTOMIE COURBES POINTUS 115MM INOX
71465	LABODERM	CISEAUX IRIDECTOMIE COURBES MOUSSES 115MM TUNGSTENE
71263	LABODERM	CISEAUX IRIDECTOMIE DROITS POINTUS 115MM INOX
71271	LABODERM	CISEAUX IRIDECTOMIE COURBES POINTUS 110MM SUPERCUT
71316	LABODERM	CISEAUX STEVENS COURBES POINTUS 140MM SUPERCUT
71268	LABODERM	CISEAUX IRIDECTOMIE COURBES MOUSSES 150MM INOX
71296	LABODERM	CISEAUX STEVENS DROITS POINTUS 140MM SUPERCUT
71295	LABODERM	CISEAUX STEVENS COURBES MOUSSES 140MM SUPERCUT
71294	LABODERM	CISEAUX STEVENS DROITS MOUSSES 140MM SUPERCUT
71261	LABODERM	CISEAUX KELLY DROITS POINTUS 140 MM INOX
71270	LABODERM	CISEAUX IRIDECTOMIE COURBES MOUSSES 110MM SUPERCUT
71269	LABODERM	CISEAUX IRIDECTOMIE DROITS POINTUS 110MM SUPERCUT
71469	LABODERM	CISEAUX IRIDECTOMIE COURBES POINTUS 115MM TUNGSTENE
71466	LABODERM	CISEAUX IRIDECTOMIE DROITS POINTUS 115MM TUNGSTENE
71483	LABODERM	CISEAUX IRIDECTOMIE DROITS MOUSSES 105MM INOX
36898	LABODERM	CISEAUX MAYO LEXER COURBES 110MM INOX
71293	LABODERM	CISEAUX METZENBAUM COURBE MOUSSES 140MM SUPERCUT
71357	GYNEAS	CISEAUX MAYO DROITS 230MM INOX
71371	GYNEAS	CISEAUX MAYO COURBES 230MM INOX
36897	LABODERM	CISEAUX MAYO LEXER DROITS 110MM INOX
7105	LABODERM	CISEAUX MEDECIN DROITS MOUSSES 140MM INOX
7109	LABODERM	CISEAUX MEDECIN DROITS POINTUS 140MM INOX
71480	LABODERM	CISEAUX KELLY COURBES POINTUS 140 MM INOX
35399	LABODERM	CISEAUX MEDECIN DROITS MOUSSES 160MM INOX
35760	GYNEAS	CISEAUX METZEMBAUM DROITS 250MM INOX
35400	LABODERM	CISEAUX METZEMBAUM DROITS 160MM INOX
35401	LABODERM	CISEAUX METZEMBAUM COURBES 160MM INOX
71491	GYNEAS	CISEAUX ALLAIN METZENBAUM DROITS 140MM INOX
71342	GYNEAS	CISEAUX ALLAINES METZEMBAUME COURBES 200MM INOX

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71328	GYNEAS	CISEAUX METZEMBAUME COUPE FILS COURBES 230MM TITANIUM
71327	GYNEAS	CISEAUX METZEMBAUME COUPE FILS COURBES 230MM INOX
71324	GYNEAS	CISEAUX METZEMBAUME COUPE FILS DROITS 230MM INOX
71343	GYNEAS	CISEAUX ALLAINES METZEMBAUME COURBES 230MM INOX
71481	LABODERM	CISEAUX DISSECTION METZENBAUM COURBES 140MM TUNGSTENE
71330	GYNEAS	CISEAUX METZEMBAUME COUPE FILS DROITS 230MM TITANIUM
71341	GYNEAS	CISEAUX ALLAINES METZEMBAUME DROITS 200MM INOX
71367	GYNEAS	CISEAUX ALLAINES METZENBAUM DROITS 230MM INOX
71484	GYNEAS	CISEAUX ALLAINE METZENBAUM COURBES 180MM INOX
7103	No Logo	CISEAUX DAUPHIN DROITS 140MM INOX
7243	LABODERM	CISEAUX ONGLE BANCAL DROITS 100MM INOX
6868	No Logo	CISEAUX LISTER CROIX ROUGE 180MM INOX
7793	LABODERM	CURETTE BESNIER FENETREE 4MM INOX
71285	GYNEAS	CANULE NOVAK 203MM Ø 3MM INOX
71470	GYNEAS	CANULE NOVAK 203MM Ø 2MM INOX
71284	GYNEAS	CANULE NOVAK 203MM Ø 2MM TITANIUM
71297	GYNEAS	CURETTE KERVORKIAN 300MM TITANIUM
71318	GYNEAS	CANULE NOVAK 203MM Ø 4MM TITANIUM
71286	GYNEAS	CANULE NOVAK 203MM Ø 3MM TITANIUM
71462	GYNEAS	CURETTE KERVORKIAN 300MM INOX
71353	LABODERM	CURETTE LUPUS BESNIER PLEINE 135MM DIAMETRE 7MM INOX
71277	LABODERM	CURETTE OPHTALMIQUE 160MM TROU DIAMETRE 1MM INOX
71333	LABODERM	GRATTOIR DE VIDAL TRANCHANT 160MM INOX
71482	LABODERM	CURETTE LUPUS BESNIER PLEIN 135MM DIAMETRE 5MM INOX
71275	LABODERM	CURETTE LUPUS BESNIER PLEINE 135 DIAMETRE 4MM INOX
71274	LABODERM	CURETTE LUPUS BESNIER PLEINE 135MM DIAMETRE 3MM INOX
71273	LABODERM	CURETTE LUPUS BESNIER PLEINE 135MM DIAMETRE 2MM INOX
71347	LABODERM	CURETTE LUPUS BESNIER PLEINE 135MM DIAMETRE 6MM INOX
71489	LABODERM	TIRE COMEDON SCHAMBERG 140MM INOX
71477	LABODERM	TIRE COMEDON BAGUE INOX
71476	LABODERM	TIRE COMEDON UNNA DOUBLES TROUS 140MM INOX
71298	GYNEAS	HYSTEROMETRE SIMS 320MM INOX
71315	GYNEAS	HYSTEROMETRE VALLLEIX FLEXIBLE 290MM INOX
2023	No Logo	MARTEAU DE BUCK INOX
1812	No Logo	ANSE DE SNELLEN 135MM INOX
1807	No Logo	ANSE DE BILLEAU PETITE 1.5x3MM INOX
1810	No Logo	ANSE DE BILLEAU MOYENNE 2x4MM INOX
1811	No Logo	ANSE DE BILLEAU GRANDE 3x5 MM INOX
7785	No Logo	LIME RAPE 4 USAGES INOX

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71329	LABODERM	PINCE DISSECTION GRAEFFE 1X2 GRIFFES DROITE 100MM INOX
1985	LABODERM	PINCE BISHOP-HARMAN COURBE SANS GRIFFE 900MM INOX
71265	LABODERM	PINCE DISSECTION OPHTALMIQUE MICRO MARTIN AVEC GRIFFES 0,35MM
7710	LABODERM	PINCE DISSECTION AVEC GRIFFES 140MM INOX
71266	LABODERM	PINCE DISSECTION OPHTALMIQUE MICRO CARLING AVEC GRIFFES 0,25MM
7738	LABODERM	PINCE DISSECTION SANS GRIFFE 140MM INOX
71332	LABODERM	PINCE A ECHARDES FEILCHENFELD 90MM INOX
71492	LABODERM	PINCE EPILER MORS BIAIS INOX
36934	LABODERM	PINCE EPILER LITTAUER INOX
6857	LABODERM	PINCE ECHARDES 115MM INOX
71352	LABODERM	PINCE DISSECTION MICRO ADSON AVEC GRIFFES 1MM 12MM INOX
71323	LABODERM	PINCE DISSECTION MICRO ADSON 0,8MM SANS GRIFFE 120MM INOX
71473	LABODERM	PINCE FINE ADSON 0.8MM DROIT SANS GRIFFE 120MM TUNGSTENE
71467	LABODERM	PINCE DISSECTION MICRO ADSON AVEC GRIFFE 1MM 12MM TUNGSTENE
71471	LABODERM	PINCE DISSECTION MICRO ADSON SANS GRIFFE 1MM 12MM TUNGSTENE
71325	LABODERM	PINCE ADSON BROWN AVEC GRIFFES 120MM INOX
71264	LABODERM	PINCE A DISSECTION FINE MICRO ADSON AVEC GRIFFES 0,65MM INOX
71478	LABODERM	PINCE JACOBSEN-ADSON SANS GRIFFE 120MM INOX
71326	LABODERM	PINCE DISSECTION GRAEFFE 1X2 GRIFFES DROITE 120MM INOX
71337	LABODERM	PINCE HEMOSTATIQUE MICROHALSTEAD COURBE SANS GRIFFE 120MM INOX
71320	LABODERM	PINCE HEMOSTATIQUE MICROHALSTEAD COURBE AVEC GRIFFE 120MM INOX
71334	LABODERM	PINCE HEMOSTATIQUE MICROHALSTEAD DROITE SANS GRIFFE 120MM INOX
71331	LABODERM	PINCE HEMOSTATIQUE MICROHALSTEAD DROITE 1X2 GRIFFES INOX
7717	LABODERM	PINCE KOCHER DROITE SANS GRIFFE 150MM INOX
71344	LABODERM	PINCE MICRO TYPE HORLOGER DROITE AVEC GRIFFES 0,35MM INOX
7719	LABODERM	PINCE KELLY DROITE SANS GRIFFE 150MM INOX
7101	No Logo	PINCE PEAN 140MM INOX
7219	LABODERM	PINCE ONGLE 14MM INOX
7220	No Logo	PINCE SECATEUR 135MM INOX
7221	LABODERM	PINCE ONGLE INCARNE 135MM INOX
1806	No Logo	PINCE HARTMANN MICRO MORS 750MM INOX
71479	LABODERM	PINCE COUPE ONGLE 100MM INOX
71485	GYNEAS	PINCE ALLIS DROITE 250MM INOX
71312	GYNEAS	PINCE ALLIS COURBE 230MM INOX
35361	No Logo	PINCE TROEL OREILLE 145MM INOX
70996	gyneas	PINCE MINI TISCHLER - MORS : 2,3X4,2MM 20CM INOX
71310	GYNEAS	PINCE MICROTISCHLER MORS 3.5X1.2MM 180MM INOX
71311	GYNEAS	PINCE MICROTISCHLER MORS 3.5X1.2MM 180MM TITANIUM
71308	GYNEAS	PINCE TISCHLER CLASSIC MORS 3X7MM 200MM INOX

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71309	GYNEAS	PINCE TISCHLER CLASSIC MORS 3X7MM 200MM TITANIUM
71307	GYNEAS	PINCE MINI TISCHLER MORS 2.3X4.2MM 200MM TITAN
71290	GYNEAS	PINCE POLYPES PALMER DROIT 220MM TITANIUM
71355	GYNEAS	PINCE POLYPES PALMER DROIT 220MM INOX
71304	GYNEAS	PINCE BENGOLEA DROITE SANS GRIFFE 240MM TITANIUM
71303	GYNEAS	PINCE BENGOLEA DROITE SANS GRIFFE 240MM INOX
71305	GYNEAS	PINCE BENGOLEA COURBE SANS GRIFFE 240MM INOX
71306	GYNEAS	PINCE BENGOLEA COURBE SANS GRIFFE 240MM TITANIUM
71464	GYNEAS	PINCE LONGUETT DROITE 240MM TITANIUM
71314	GYNEAS	PINCE POZZI PALMER FINE 235MM INOX
71291	GYNEAS	PINCE POZZI PALMER FINE 235MM TITANIUM
71289	GYNEAS	PINCE TERRHUN DEMONTABLE 270MM TITANIUM
71287	GYNEAS	PINCE CICERON STERILET 210MM INOX
71313	GYNEAS	PINCE TERRHUN DEMONTABLE 270MM INOX
71288	GYNEAS	PINCE CICERON STERILET 210MM TITANIUM
71475	GYNEAS	CROCHET DIU 260MM TITANIUM
71283	GYNEAS	CROCHET DIU 260MM INOX
71345	LABODERM	PORTE AIGUILLE HEMOSTATIQUE NESSICARE DROIT 140MM INOX
6844	LABODERM	PORTE AIGUILLE MAYO HEGAR 140MM INOX
71364	LABODERM	PORTE AIGUILLE HALSEY ULTRAFIN DROIT 130MM INOX
71340	LABODERM	PORTE AIGUILLE HEMOSTATIQUE NESSICARE DROIT 100MM INOX
71361	LABODERM	PORTE AIGUILLE NESSICARE DROIT QUADRILLE 120MM INOX
71359	LABODERM	PORTE AIGUILLE HALSEY DROIT 130MM INOX
71463	LABODERM	PORTE AIGUILLE HALSEY DROIT MORS QUADRILLES 130MM TUNGSTENE
71362	LABODERM	PORTE AIGUILLE NESSICARE DROIT QUADRILLE 140MM INOX
71468	LABODERM	PORTE AIGUILLE-CISEAUX OLSEN-HEGAR DROITS 120MM TUNGSTENE
71360	LABODERM	PORTE AIGUILLE OLSEN HEGAR DROIT 140MM INOX
71472	LABODERM	PORTE AIGUILLE-CISEAUX OLSEN-HEGAR DROITS 140MM TUNGSTENE
71363	LABODERM	PORTE AIGUILLE HEMOSTATIQUE NESSICARE DROIT 120MM INOX
37558	LABODERM	PORTE AIGUILLE MAYO HEGAR 140MM INOX
71302	GYNEAS	SPECULUM COHEN 4VALVE PETIT 23MM TITANIUM
71299	GYNEAS	SPECULUM COHEN 4VALVE GRAND 34,5 MM INOX
71300	GYNEAS	SPECULUM COHEN 4VALVE GRAND 34,5MM TITANIUM
71301	GYNEAS	SPECULUM COHEN 4VALVE PETIT 23 MM INOX
71356	GYNEAS	SPECULUM KOGAN CREMAILLERE 240MM TITANIUM
71493	LABODERM	COFFRET 4 INSTRUMENTS TUNGSTENE
71494	LABODERM	MANCHE GREFFE DE CHEVEUX EASY GREFF'
71281	LABODERM	CROCHET GILLIES FIN 190MM INOX
71282	LABODERM	CROCHET GILLIES STANDARD 190MM INOX

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2341	LABODERM	CUPULE 12.5CL DIAMETRE 80MM INOX
2355	LABODERM	CUVETTE RENIFORME BORD ROULE 170X95MM INOX
2356	LABODERM	CUVETTE RENIFORME BORD FRANC 250X135MM INOX
2342	LABODERM	CUPULE 25 CL DIAMETRE 100MM INOX
2339	LABODERM	CUPULE 7.5CL DIAMETRE 60MM INOX
6882	LABODERM	STYLET PORTE COTON 140MM POUR ORL INOX

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