Tel : 92-52-3551358-3557709
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Y.B.SURGICO
Qamar Market Street, Green Town,
Near Sublime Chowk, Sialkot, Pakistan.

Doc.# DOC-21-01
Rev-03

Date.12-12-2020
Rev Date: 23-06-2025

EU Declaration of Conformity

We YB Surgico,
Sialkot Pakistan

Declare under our sole responsibility that the product(s)
Reusable Surgical Instruments including

List of articles attached as per Annex A

Medical Device Class: I (Reusable)

Classification based on MDD 93/42/EEC updated directive 2007/47/EEC, Annex IX, Chapter 3, Subsection 2.2, Rule 6 is class I.
"All surgically invasive devices intended for transient use are in Class IIa unless they are:
— reusable surgical instruments, in which case they are in Class I;"

Conformity Assessment

Conformity assessment procedure for C*lass I: as per Article 11 Section 5* of the Medical Device Directive 93/42/EEC by drawing up declaration of conformity & technical documentation as per Annex VII for the products.

The above-mentioned products comply to the following standards:

ISO 9001:2015	EN ISO 13485:2016	ISO 17664:2017
EN ISO 7153-1:2016	EN ISO 10993-1:2018	EN 1041:2008+A1:2013
EN ISO 15223-1:2021	EN ISO 10993-05:2009	BS EN ISO 17665-1:2006
EN ISO 14971:2019	EN ISO 10993-10:2021	EN ISO 13402:2000
EU Directive 93/42/EEC updated directive 2007/47/EEC,		ISO 11135:2014

CE

EC REP

CMC Medical Devices & Drugs S.L
C/ Horacio Lengo n18, C.P 29006
Málaga-Spain
Phone: +34 951 214 054
Email: info@cmcmedicaldevices.com

This declaration is valid until a new revision is issued.

Signature PRRC/Manager Q.A (KS Faisal)
Sialkot Pakistan
10-02-2024

MDD DOC (Extended as per EU Regulations 2023/607 through notified letter letter CLNB1639 - PK/SKT/233941 till **(31st December 2028)**

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Y.B. Surgico **Item Code**	***Y.B. Surgico*** **Item Name**	***Servoprax*** **item code**
Y08.031.25bR	Gross-Maier Dressing and Cotton Swab Forceps Cvd 25cm	I5 001
Y05.015.14bR	Operating Scissors Cvd Sh/Sh 14.5cm	I5 003
Y08.030.25bR	Gross-Maier Dressing and Cotton Swab Forceps Str 25cm	I5 007
Y08.031.20bR	Gross-Maier Dressing and Cotton Swab Forceps Cvd 20cm	I5 008
Y08.030.20bR	Gross-Maier Dressing and Cotton Swab Forceps Str 20cm	I5 009
Y07.226.14bR	Pean(Ochsner)Artery Forceps Str 14cm	I5 010
Y07.220.14bR	Pean(Rochester)Artery Forceps Str 14cm	I5 011
Y06.376.11bR	Feilchenfeld Splinter Forceps 11.5cm	I5 012
Y06.376.09bR	Feilchenfeld Splinter Forceps, 9.0 cm	I5 013
Y06.114.14bR	Tissue Forceps Regular 1:2 Teeth 14cm	I5 014
Y06.010.14bR	Dressing Forceps Standard 14.5cm	I5 015
Y05.145.11bR	Iris Scissor Cvd 11.5cm	I5 019
Y05.144.11bR	Iris Scissor Str 11.5cm	I5 020
Y05.014.14bR	Operating Scissors Str Sh/Sh 14.5cm	I5 023
Y05.012.14bR	Operating Scissors Str Sh/Bl 14.5cm	I5 024
Y05.011.14bR	Operating Scissors Cvd Bl/Bl 14.5cm	I5 025
Y05.010.14bR	Operating Scissors Str Bl/Bl 14.5cm	I5 026
Y05.144.13bR	Iris Scissor Str 13cm	I5 027
Y08.402.25bR	Magill Catheter Introducing Forceps 25 cm	I5 030
Y08.402.20bR	Magill Catheter Introducing Forceps 20 cm	I5 031
Y05.145.13bR	Iris Scissor Cvd 13cm	I5 028
Y05.013.14bR	Operating Scissors Cvd Sh/Bl 14.5cm	I5 037
Y06.010.13bR	Dressing Forceps Standard 13cm	I5 061
Y06.010.16bR	Dressing Forceps Standard 16cm	I5 062
Y05.820.11R	Spencer Ligature Scissor 11cm	I5 063
Y07.220.16bR	Pean(Rochester)Artery Forceps Str 16cm	I5 064
Y07.226.16bR	Pean(Ochsner)Artery Forceps Str 16cm	I5 065
Y07.220.18bR	Pean(Rochester)Artery Forceps Str 18cm	I5 066
Y12.050.16bR	Mayo-Hegar Needle Holders Str 16cm	I5 068
Y12.200.14R	Mathieu Needle Holders 14cm	I5 069

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Y07.060.12bR	Halsted-Mosquito Artery Forceps Str 12.5cm	I5 075
Y07.061.12bR	Halsted-Mosquito Artery Forceps Cvd 12.5cm	I5 076
Y08.402.15bR	Magill Catheter Introducing Forceps 15 cm	I5 105
Y12.200.17R	Mathieu Needle Holders 17cm	I5 115
Y12.050.18bR	Mayo-Hegar Needle Holders Str 18cm	I5 116
Y15.344.20R	Volkmann Bone Curettes 17cm Fig.00	I5 143
Y15.344.10R	Volkmann Bone Curettes 17cm Fig.0	I5 144
Y15.344.01R	Volkmann Bone Curettes 17cm Fig.1	I5 145
Y15.344.02R	Volkmann Bone Curettes 17cm Fig.2	I5 146
Y15.344.03R	Volkmann Bone Curettes 17cm Fig.3	I5 147
Y12.460.12R	Michel Suture Instruments 12.5cm	I5 200
Y07.700.14bR	Standard Tubing Clamp Artery Forceps 14cm	I5 154
Y07.700.16bR	Standard Tubing Clamp Artery Forceps 16cm	I5 155
Y08.090.27R	Ulrich Dressing and Cotton Swab Forceps Str 27cm	I5 209
Y07.500.20R	Mikulicz Peritoneal Clamps Forceps 20cm	I5 211
Y22.294.12R	Troeltsche (Wilde) Ear Dressing Forceps 12cm	I5 214
Y06.246.12R	Adson Tissue Forceps 1:2 Teeth 12cm	I5 215
Y06.066.12bR	Adson Dressing Forceps 12cm	I5 216
Y06.370.09R	Splinter Forceps With Magnifying Glass 9cm	I5 217
Y06.028.11R	Ochsner Dressing Forceps Str , Str 11cm	I5 227
Y06.380.12bR	Splinter Forceps 12.5cm	I5 229
Y06.381.13bR	Splinter Forceps 12.5cm cvd	I5 611
Y06.010.20bR	Dressing Forceps Standard 20cm	I5 619
Y07.220.20bR	Pean (Rochester)Artery Forceps Str 20cm	I5 0660
Y05.012.13bR	Operating Scissors Str Sh/Bl 13cm	I5 683
Y05.014.11bR	Operating Scissors Str Sh/Sh 11.5cm	I5 688
Y05.014.13bR	Operating Scissors Str Sh/Sh 13cm	I5 689
Y05.014.16bR	Operating Scissors Str Sh/Sh 16.5cm	I5 690
Y05.015.11bR	Operating Scissors Cvd Sh/Sh 11.5cm	I5 691
Y05.015.13bR	Operating Scissors Cvd Sh/Sh 13cm	I5 692
Y05.010.11bR	Operating Scissors Str Bl/Bl 11.5cm	I5 694
Y05.142.09bR	Iris Scissor Str 9cm	I5 703
Y05.143.09bR	Iris Scissor Cvd 9cm	I5 704

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Y12.170.14bR	Olsen Hegar Needle Holders 14cm	I5 707
Y12.170.17bR	Olsen Hegar Needle Holders 17cm	I5 708
Y12.170.19bR	Olsen Hegar Needle Holders 19cm	I5 709
Y11.010.13R	Probes 14cm 1.5mm	I5 716
Y15.344.30R	Volkmann Bone Curettes 17cm Fig.000	I5 722
Y15.344.40R	Volkmann Bone Curettes 17cm Fig.0000	I5 723
Y15.364.01R	Williger Bone Curettes 13.5cm Fig.00 + 0	I5 724
Y15.364.02R	Williger Bone Curettes 13.5cm Fig.0 + 1	I5 725
Y31.580.25R	Schroeder Tenaculum Forceps 25.0cm	I5 742
Y08.102.45R	IUP Grasping Forcep, 1:2 teeth, 4.5 cm	I5 743
Y22.370.02R	Billeau Loops, Foreign Body Instruments Hooks 16.5cm	I5 752
Y31.786.28R	Alexander Cervical Biopsy and Specimen Forceps 28.0cm	I5 754
Y31.790.01R	Schumacher Cervical Biopsy and Specimen Forceps 24.0cm	I5 755
Y31.804.01R	Townsend-Tischler Morgan Cervical Biopsy and Specimen Forceps Fig. 1 compl. Instrument	I5 756
Y10.086.13R	Weitlaner Self Retaining Retractors Blunt 13cm	I5 772
Y10.082.10R	Weitlander-Loktite Self Retaining Retractors Blunt 35mm 10cm	I5 773
Y10.086.16R	Weitlander Self Retaining Retractors Blunt 16cm	I5 774
Y05.012.14R	Operating Scissors Str Sh/Bl 14.5cm	R2 001
Y05.014.14R	Operating Scissors Str Sh/Sh 14.5cm	R2 002
Y05.380.23R	Metzenbaum-Nelson Scissor Bl/Bl Str 23cm	R2 012
Y05.381.23R	Metzenbaum-Nelson Scissor Bl/Bl Cvd 23cm	R2 016
Y06.010.11R	Dressing Forceps Standard 11.5cm	R2 021
Y06.010.13R	Dressing Forceps Standard 13cm	R2 022
Y06.010.14R	Dressing Forceps Standard 14.5cm	R2 023
Y06.010.18R	Dressing Forceps Standard 18cm	R2 024
Y06.114.11R	Tissue Forceps Regular 1:2 Teeth 11cm	R2 025
Y06.114.13R	Tissue Forceps Regular 1:2 Teeth 13cm	R2 026
Y06.114.14R	Tissue Forceps Regular 1:2 Teeth 14cm	R2 027
Y06.116.14R	Tissue Forceps Regular 2:3 Teeth 14cm	R2 030
Y06.066.12R	Adson Dressing Forceps 12cm	R2 032
Y06.376.07R	Feilchenfeld Splinter Forceps 7.5cm	R2 034

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Y06.376.09R	Feilchenfeld Splinter Forceps 9cm	R2 035
Y06.376.11R	Feilchenfeld Splinter Forceps 11.5cm	R2 036
Y05.142.09R	Iris Scissor Str 9cm	R2 037
Y05.144.11R	Iris Scissor Str 11.5cm	R2 038
Y05.143.09R	Iris Scissor Cvd 9cm	R2 039
Y05.145.11R	Iris Scissor Cvd 11.5cm	R2 040
Y07.220.14R	Pean (Rochester)Artery Forceps Str 14cm	R2 054
Y07.220.18R	Pean (Rochester)Artery Forceps Str 18cm	R2 056
Y12.200.14tcR	Mathieu Needle Holders W/TC 14cm	R2 074
Y12.200.17tcR	Mathieu Needle Holders W/TC 17cm	R2 075
Y07.120.14tcR	Crile Wood Baby Needle Holder W/TC 15 cm	R2 077
Y12.304.18tcR	Castroviejo Micro-Needle Holders Str W/TC 18cm(With Ratchet)	R2 078
Y12.143.18tcR	Debakey Needle Holder W/TC 18 cm	R2 079
Y12.170.14tcR	Olsen Hegar Needle Holders W/TC 14cm	R2 082
Y12.186.18tcR	Langenbeck Needle Holders W/TC 18cm	R2 087
Y07.692.18R	Tubing Clamp Artery Forceps 18cm	R2 094
Y07.061.12R	Halsted-Mosquito Artery Forceps Cvd 12.5cm	R2 104
Y07.031.10R	Hartmann Artery Forceps Cvd 10cm	R2 106
Y07.030.10R	Hartmann Artery Forceps Str 10cm	R2 107
Y08.030.25R	Gross-Maier Dressing and Cotton Swab Forceps Str 25cm	R2 110
Y09.250.03R	Volkmann Retractor Sharp 3 Prongs 21.5cm	R2 139
Y05.700.21R	Umbilical, Episiotomy and Enterotomy Scissor 21cm	R2 143
Y15.344.10R	Volkmann Bone Curettes 17cm Fig.0	R2 146
Y05.674.16R	Schumacher Umbilical, Episiotomy and Enterotomy Scissor 15.5cm	R2 170
Y06.010.20R	Dressing Forceps Standard 20cm	R2 202
Y12.262.14tcR	Castroviejo Micro-Needle Holders Str W/TC 14cm	R2 0781
Y05.143.09tcR	Iris Scissor Cvd 9cm Tc	R2 039-WD
Y12.050.16tcR	Mayo-Hegar Needle Holders Str 16cm Tc	R2 071
Y12.050.18tcR	Mayo-Hegar Needle Holders Str 18cm Tc	R2 072
Y05.144.11tcR	Iris Scissor Str 11.5cm Tc	R2 038-WD
Y05.341.14tcR	Metzenbaum Scissor Bl/Bl Cvd 14.5cm Tc	R2 201-WD