Tel : 92-52-3551358-3557709
Fax : 92-52-3557705
E-mail : exports@ybsurgico.com.pk
: info@ybsurgico.com.pk
Web : www.ybsurgico.com.pk

Y.B.SURGICO
Qamar Market Street, Green Town,
Near Sublime Chowk, Sialkot, Pakistan.

Doc.# DOC-24-01 Date.15-05-2025

EU Declaration of Conformity

We YB Surgico,
Sialkot Pakistan

Declare under our sole responsibility that the product(s)
Surgical & Gynecology Instruments including:

List of articles attached as per Annex A

Medical Device Class: I (Reusable)

Classification based on MDR 2017/745 Annex VIII, Chapter 3, Paragraph 5, Rule 5 is class I.
"*All invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active device or which are intended for connection to a class I active device are classified as:*
— *class I if they are intended for transient use;*"

Conformity Assessment

Conformity assessment procedure for C*lass I: as per Chapter V Article 52 Section 7* of the Medical Device Regulation (EU) 2017/745 by declaration of conformity for the products after drawing up of technical documentation as per Annex II and III.

The Medical Device referenced above meets the provisions of Regulation (EU) 2017/45 on medical devices.
The above-mentioned products comply to the following standards:

ISO 9001:2015	EN ISO 13485:2016	ISO 17664-1:2021
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
MDR 2017/745 Annex I-VI, VIII		ISO 11135:2014

Common Specification: -

There are no commons specifications published in EU for these article

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.

SLH

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

Tel : 92-52-3551358-3557709
Fax : 92-52-3557705
E-mail : exports@ybsurgico.com.pk
: info@ybsurgico.com.pk
Web : www.ybsurgico.com.pk

Y.B. SURGICO
Qamar Market Street, Green Town,
Near Sublime Chowk, Sialkot, Pakistan.

Y.B. Surgico **Item Code**	***Y.B. Surgico*** **Item Name**	***Servoprax*** **item code**
Y04.104.03R	Scalpel Handle #3	I1 0603
Y04.120.04R	Scalpel Handle #4	I1 0604
Y13.080.18bR	Utility Bandage Scissors18 cm black	I5 002
Y15.105.01R	Doctor Instrument Set	I5 006
Y13.010.18bR	Lister Bandage Scissor 18cm	I5 016
Y13.010.16bR	Lister Bandage Scissor 16cm	I5 017
Y13.010.14bR	Lister Bandage Scissor 14cm	I5 018
Y13.010.20bR	Lister Bandage Scissor 20cm	I5 032
Y31.020.01R	Cusco Vaginal Specula 75x32mm	I5 043
Y31.020.02R	Cusco Vaginal Specula 85x35mm	I5 044
Y31.020.03R	Cusco Vaginal Specula 100x35mm	I5 045
Y13.114.28R	Henning Plaster Cast Instruments 28cm	I5 058
Y13.010.11bR	Lister Bandage Scissor 11cm	I5 060
Y31.140.02R	Kristeller Vaginal Specula and Retractors 110x30mm specula	I5 134
Y31.140.03R	Kristeller Vaginal Specula and Retractors 110x36mm specula	I5 135
Y31.120.01R	Kristeller Vaginal Specula and Retractors Fig1 110x18mm specula	I5 170
Y31.120.02R	Kristeller Vaginal Specula and Retractors Fig2 110x21mm specula	I5 171
Y13.080.18RR	Utility Bandage Scissors18 cm Red	I5 226
Y06.438.09R	Cilia Forceps 8.5cm	I5 230
Y15.267.17R	Excavator, 17 cm	I5 267
Y15.268.14R	Retractor 14 cm	I5 268
Y13.080.18BLR	Utility Bandage Scissors 18 cm blue	I5 400
Y23.030.03bR	Hartmann Hale Nasal Specula Fig.3 15cm	I5 726
Y22.630.61R	Tuning Forks a i 440	I5 727
Y01.130.19R	Wartenberg Sensibility 19cm	I5 728
Y31.472.32R	Sims Uterine Sounds malleable 32cm	I5 740
Y08.100.01R	Eye Magnet with Magnifying glass & plastic handle	I5 758
Y22.404.02R	Lucae Hooklets 14cm	I5 765
Y26.464.28R	Michel Laryngeal Handles and Mirors 25.0cm fig.9 28mm ϕ	I5 803

Tel : 92-52-3551358-3557709
Fax : 92-52-3557705
E-mail : exports@ybsurgico.com.pk
: info@ybsurgico.com.pk
Web : www.ybsurgico.com.pk

Y.B.SURGICO
Qamar Market Street, Green Town,
Near Sublime Chowk, Sialkot, Pakistan.

Y26.464.30R	Michel Laryngeal Handles and Mirors 25.0cm fig.10 30mm ϕ	I5 804
Y01.046.18R	Buck Hammer 18cm	I5 840
Y01.034.24R	Troemner Hammer 24cm 175 gm	I5 845
Y01.040.20R	Berliner Hammer 20cm	I5 850
Y01.010.18R	Taylor Hammer 18cm	I5 855
Y01.076.23R	Babinsky Hammer 22cm With out Needle	I5 865
Y22.170.12R	Hartmann Ear Polypus Forceps Length of shaft 12cm	R2 047
Y23.030.01R	Hartmann Hale Nasal Specula Fig.1 15cm	R2 049
Y23.030.02R	Hartmann Hale Nasal Specula Fig.2 15cm	R2 050
Y23.030.03R	Hartmann Hale Nasal Specula Fig.3 15cm	R2 051
Y24.060.13R	Heister Mouth Gags 13.0cm	R2 053
Y13.010.14R	Lister Bandage Scissor 14cm	R2 115
Y13.010.18R	Lister Bandage Scissor 18cm	R2 116
Y13.010.20R	Lister Bandage Scissor 20cm	R2 117
Y30.147.12R	Strauss, Genito-Urinary Instruments 12cm	R2 144
Y13.010.16R	Lister Bandage Scissor 16cm	R2 211