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

Doc.# DOC-21-01
Rev-02

Date.12-12-2020
Rev Date: 10-12-2024

EU Declaration of Conformity

We YB Surgico,
Sialkot Pakistan

SRN PK-MF-000041619

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

BASIC UDI Splinter Forceps Feilchenfeld 11.5cm (Non-Sterilized) ++G615SPLINTERFORCEPSQP

Intended Use: A Splinter Forceps Feilchenfeld is a medical device surgeons use to place or remove wound closure adhesive strips.

Article Name	Article Code	Article Code Sohngen
Splinter Forceps Feilchenfeld 11.5cm	Y06.376.11	2001110

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

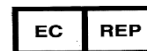
Conformity assessment procedure for *Class I: as per Article 11 Section 5* of the Medical Device Directive 93/42/EEC by drawing up declaration of conformity & technical documentation as per Annex VII for the products.

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



This declaration is valid until a new revision is issued.



SRN # ES-AR-000000293

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Manufacturers, Exporters & Importers of Fine Quality Surgical, Dental, T.C Instruments & all Scissors



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SLH

Signature PRRC/Manager Q.A (K.S 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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