



EC Certificate Full Quality Assurance System: GB06/67327.01

The management system of

**M.A Arain & Brothers Pvt. Ltd.**

Wazirabad Road, Sialkot, Pakistan

has been assessed and certified as meeting the requirements of

**Directive 93/42/EEC**  
on medical devices, Annex II (excluding Section 4)

For the following products

**The scope of registration appears on page 2 of this certificate.**

This certificate is valid from 17 February 2015 until 06 February 2020 and remains valid subject to satisfactory surveillance audits.  
Re certification audit due before 06 February 2018  
Issue 10. Certified since 06 February 2006

Certification is based on reports numbered GB/PI 211230

Multiple certificates have been issued for this scope  
The main certificate is numbered GB06/67327.00

Authorised by

**SGS United Kingdom Ltd, Notified Body 0120**

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SGS CE 01 0311 M2

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**M.A.Arain & Brothers Pvt. Ltd.**

**Directive 93/42/EEC**  
on medical devices, Annex II (excluding section 4)

Issue 10

Detailed scope

Sterile / Non-Sterile Single Use Electrosurgical Bipolar Forceps with and without cables & non stick Tips. Sterile / Non-Sterile Single Use Electrosurgical Monopolar Forceps with and without cables. Sterile / Non-Sterile Single Use Electrosurgical Pencils with loops, electrodes, Endo hooks, Non stick Electrodes and smoke evacuator. Sterile / Non-Sterile Single Use Electrosurgical Monopolar Laparoscopic Instruments. Sterile / Non-Sterile Single Use Surgical Trocars with and without Blade. Non Sterile Reusable Electrosurgical Bipolar Forceps with and without Cables, Non Sterile Reusable Electrosurgical Monopolar Forceps with and without Cables, Non Sterile Reusable Electrosurgical Bipolar electrodes. Non Sterile Reusable Electrosurgical Monopolar electrodes. Sterile / Non Sterile Singe use Surgical Forceps. Sterile / Non Sterile Singe use Surgical Scissors. Sterile / Non Sterile Singe use Surgical Tweezers. Sterile / Non Sterile Singe use Surgical Retractors. Sterile / Non Sterile Single Use Scalpel Handles without Blade

For placing on the market of Class III devices covered by this certificate, an EC-Design Examination Certificate according to Annex II (Section 4) is required.



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Certificate GB05/64067.01, continued



**M.A.Arain & Brothers Pvt. Ltd.**

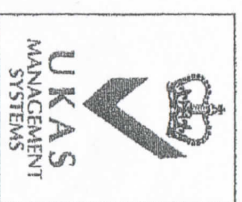
**ISO 13485:2003**  
**EN ISO 13485:2012**



Issue 11

Detailed scope

**Design, Manufacturing & Sales of Sterile & Non Sterile Single use & Non Sterile Reusable Surgical, Dental, Diagnostic and Electrosurgical Instruments**



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