



M.A. ARAIN & BROTHERS (PVT.) LTD.

Manufacturers & Exporters of fine quality Surgical & Dental Instruments

DECLARATION OF COMPLIANCE

DOC NO: MA/0012/01/00

Product quality parameters and intended use is our primary objectives for serving best to the human beings, All products are manufactured at **M. A. Arain & Brothers (Pvt.) Ltd** with controlled quality Management System in accordance with ISO 9001:2008 and tested at final by the Quality Assurance personnel using product's specification and tested against EN 10204.

AISI 304 Austenitic (EN 10088-3:2005)

DIN : X5CrNi18-10 Din Reference : 1.4301

Product Description and Chemistry

Product Cat Number

Tweezer Fish Type				30.035.13		
Carbon	Chromium	Manganese	Nickel	Phosphorus	Sulphur	Silicon
0.08	18-20	2 max	8-10.5	0.045 max	0.03 max	1max

AISI 410 Martensitic (EN 10088-3: 2005)

DIN : X15Cr13 Din Reference : 1.4124

Product Description and Chemistry

Laksetang plier serrated jaw 16 cm				31.142.16		
Thumb dressing forceps 30 cm				44.0360.30		
Thumb dressing forceps 40 cm				44.0362.40		
Semken Dressing Forceps 12cm straight				44.0102.12		
Semken Dressing Forceps 12cm curved				44.0103.12		
Carbon	Chromium	Manganese	Phosphorus	Silicon	Sulphur	HRC
0.15 max	11.5 -13.5	1 max	0.04 max	1 max	0.03 max	42-46

All material properties have been verified against chemical composition by the registered and accredited lab (PCSIR) Lahore. Pakistan with the compliance of the steel certificate.

(Stainless steel)products can be cleaned as per requirements of the hotel Management and household utensils But we recommend steam sterilization at 134 Centigrade for 25 minutes.

All products have been treated according to ASTM a 380, passivation is "the removal of exogenous iron or Iron compounds from the surface of a stainless steel by means of a chemical dissolution most typically by a Treatment with an acid solution that will remove the surface contamination but will not significantly affect the Stainless steel itself"

All product are made off (Biocompatible stainless steel) that is totally safe user and environment.

For M.A.Arain & Brothers (Pvt.) Ltd

QA Manager.



Date: 19.10.2013



MEMBERS



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M.A. ARAIN & BROTHERS (PVT.) LTD.

Manufacturers & Exporters of fine quality Surgical & Dental Instruments

DECLARATION OF CONFORMITY

Doc No: MA/0012/02/00

Product quality parameters and its intended use is our primary objectives for serving best to the Human beings, All products are manufactured at M.A. Arain & Brothers (Pvt.) Ltd with controlled quality management system in accordance with ISO 9001: 2008 and tested at final by the quality assurance personnel using product's specification. Product specifications are met according to the international standards for stainless steel and production processes are run according to the developed work instructions. Rust, pitting and corrosion are tested at M.A. Arain & Brothers (Pvt.) Ltd according to the harmonized standards.

All products are made off grade stainless steel that is totally safe for human and environment. **Thumb Dressing Forceps, Laksetang Plier Serrated jaw and Tweezers Fish Types, Semken Dressing Forceps,** are subjected to the conformity:

Mentioned above products fall in class I according to the following Directive/Regulations:

- COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning medical devices
- REGULATION (EC) No 1935/2004 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC
- COMMISSION REGULATION (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food

M.A. Arain & Brothers strives to maintain its prestige by implementing QMS and promoting products functions by selecting objective of the Research and Development.

For M.A. Arain & Brothers (Pvt) Ltd

QA Manager.



Date: 19.10.2013

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