



## Agile Industries is certified for given below Organizations:-

- 1-Certified for International Quality and Management System ISO:9001:2000.
- 2- Certified for Medical Devices ,Dental and Surgical Instruments according to the International Standard.ISO:13485:2003.
- 3-Certified for CE MARKING Declaration as per Council Directive 93/42 EEC and update directives of Medical Devices for class-1
- 4-Member of Chamber of Commerce & Industry in Sialkot Pakistan.
- 5-Member of Surgical Instruments manufacturers Association of Pakistan.
- 6-Certified for FREE SALE all over the world.

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## DECLARATION OF CONFORMITY

We,

### **AGILE Industries**

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Hereby declare that we fall within manufacturers of Class – I devices and the devices produced by us are

- **Surgical Instruements** (Single Use, Re-useable)
- **Dental Instruments** (Single Use, Re-useable)

Meet the essential requirement of Directive No. 93/42/EEC and updated directive 2007/47/EEC. We prepare and maintain technical documentation for each device as requires by rule 6, Annex-VII of the directive.

To which this declaration related is in conformity with the following standard(s) or other normative document(s)

ISO 13485	Medical Devices-Quality Management Systems-Requirements for Regulatory Purpose
ISO 9001	Quality Management Systems
ISO 14971	Medical Devices-Application of Risk Management to Medical Devices
ISO 17665	Sterilization of Medical Devices-Information to be provided by the manufacturer for the processing of re-sterilizable medical devices
EN ISO 15223-1	Graphical Symbols for Use in the Labeling of Medical Devices
cGMP	Medical Devices; Current Good Manufacturing Practice
93/42/EEC	Council Directive for Medical Devices
ASTM-F899	Standard Specification for Stainless Steel Billet, Bar, and Wire for Surgical Instruments
ISO 7153-1	Surgical Instruments – Metallic Materials – Part 1: Stainless Steel



**Managing Partner**

**AGILE Industries**

**MUHAMMAD SALEEM**



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