

## **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.

Ph: +92 52 3256926  
Fax: +92 52 3256927  
Email: [sales@agileindustries.com](mailto:sales@agileindustries.com)  
[www.agileindustries.com](http://www.agileindustries.com)

## **DECLARATION OF CONFORMITY**

We,

**AGILE Industries**

Street#32,New Miana Pura (west ), Roras Road Sialkot –Pakistan.

[Tel:+92-52-3256926](tel:+92-52-3256926) Fax: +92-52-3256927 Email: [info@agileindustries.com](mailto:info@agileindustries.com)

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**

