



August 1, 2017

EC DECLARATION OF CONFORMITY

We,

AR INSTRUMED

Airport Road Gohad Pur, Sialkot 51310 PAKISTAN.

Tel: +92 52 427 3171 Fax: +92 52 427 3171

Mob: +92 308 888 05 88 WEB: www.ar-instrumed.com EMail: info@ar-instrumed.com

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

➤ **Dental Instruments.**

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 another 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

Signature


Manager QA

A To 2



ĐẠI SỨ QUÁN CHXHCN VIỆT NAM TẠI C.H HỜI GIÁC PAKISTAN
EMBASSY OF THE S.R OF VIETNAM IN THE I. R OF PAKISTAN

CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ
CONSULAR AUTHENTICATION

1. Quốc gia: Việt Nam
Country
2. do Ông (Bà): Muhammad Yasin Malik ký
Giấy tờ, tài liệu này
This public document
has been signed by
3. với chức danh: Trợ lý Vụ trưởng Lãnh sự
acting in the capacity of
4. và con dấu của: Bộ Ngoại giao Pakistan
bears the stamp of
tại: Islamabad
được chứng nhận / hợp pháp hóa lãnh sự
Certified
5. tại Islamabad
at
6. ngày 18 / 5 / 2017
the
7. Cơ quan cấp: Đại sứ quán Việt Nam tại Pakistan
by
8. Số: 35817 /HPHLS
N°

Ký tên và đóng dấu
Signature and seal/stamp
Consular Officer



Phạm Thị Trung