

DECLARATION OF CONFORMITY

| Manufacturer: | Surgicon (Pvt) Ltd.P.O Box: 244 Khadim Ali Road Sialkot-Pakistan | | | | |
|--|---|------------------------------|------------------|-------|----------|
| European Representative | Dynamics Certification Organization | | | | |
| Products (s) | | | | | |
| | S.No. | Products Name | Product Code | CLASS | Material |
| | 01 | Canulated Srew Driver 3.5 mm | Jo-21-25920 | Class | AISI 410 |
| | 02 | Hexagon Screw Driver 2.5 mm | Jo-21-2581 | 1 | AISI 420 |
| | 03 | Hexagon Screw Driver 3.5 mm | Jo-21-2586 | | AISI 420 |
| Classification | MDD93/42/ECC Annex IX, Rule 8, Class I | | | | |
| Conformity Assessment Route: | Annex I, Self declaration of conformity for CE Marking | | | | |
| We herewith declare that the product (s) mentioned above meets (s) the provisions of the council Directive 93/42/EEC concerning medical devices .File of technical documentation is kept under the premises of the Manufacturer. | | | | | |
| Applicable Standards. | MDD93/42/EEC, EN/ISO 13485-2012, EN/ISO 14971-2012,ISO 15223-1-2012 | | | | |
| | MEDDEV 2.4/1 Rev-09, EN 62366:2008,IASO 14644-1:2015. | | | | |
| Place & Date Of Issue | Surgicon (Pvt) Ltd. PO Khadim Ali Road Sialkot-Pakistan 31/08/2017 | | | | |
| Responsible Person. | Arshad | Malik | | | |
| Lot No: | ISCL-13 | 1-55734 S | Sign: Fizan jila | ani | |

Surgicon (Pvt) Ltd Director