

## EC DECLARATION OF CONFORMITY

We, M/s. **Ziana Industries, Islam Nagar Road, Pacca Garah, Sialkot - 51310-Pakistan** under sole responsibility declares that the below mentioned devices have been classified as class I reusable medical devices according to the classification rules stated in the Annex–IX and conform to the Essential Safety and Performance as laid out in the Annex– I of Council Directive 93/42/EEC as amended by Directive 2007/47/EC for medical devices given in Annex A to this document meet the essential requirement of Directive No. 93/42/EEC and updated directive 2007/47/EC.

Each type of medical device to which the technical documentation complies with the applicable provisions of the essential principles and following mentioned harmonized standards. The following mentioned products fall within Class –I medical devices and the devices produced by us are as under:

| Sr. No. | Item Codes | Item Description                | Risk Class | Usability |
|---------|------------|---------------------------------|------------|-----------|
| 1       | 29 365 00  | UNNA CURETTE                    | Class I    | Reusable  |
| 2       | 33 500 00  | SPLINTER WITH MAGNIFYING GLASS  | Class I    | Reusable  |
| 3       | C1 001 11  | OPERATING SCISSORS B/B STRAIGHT | Class I    | Reusable  |
| 4       | C1 001 14  | OPERATING SCISSORS B/B STRAIGHT | Class I    | Reusable  |
| 5       | C1 001 16  | OPERATING SCISSORS B/B STRAIGHT | Class I    | Reusable  |
| 6       | C1 001 18  | OPERATING SCISSORS B/B STRAIGHT | Class I    | Reusable  |
| 7       | C1 002 14  | OPERATING SCISSORS B/S STRAIGHT | Class I    | Reusable  |
| 8       | C1 002 16  | OPERATING SCISSORS B/S STRAIGHT | Class I    | Reusable  |
| 9       | C1 002 18  | OPERATING SCISSORS B/S STRAIGHT | Class I    | Reusable  |
| 10      | C1 003 14  | OPERATING SCISSORS S/S STRAIGHT | Class I    | Reusable  |
| 11      | C1 003 16  | OPERATING SCISSORS S/S STRAIGHT | Class I    | Reusable  |
| 12      | C1 011 14  | OPERATING SCISSORS B/B CURVED   | Class I    | Reusable  |
| 13      | C1 021 14  | OPERATING SCISSORS B/S CURVED   | Class I    | Reusable  |
| 14      | C1 031 14  | OPERATING SCISSORS S/S CURVED   | Class I    | Reusable  |
| 15      | C1 040 14  | METZENBAUM SCISSORS STRAIGHT    | Class I    | Reusable  |
| 16      | C1 041 14  | METZENBAUM SCISSORS CURVED      | Class I    | Reusable  |
| 17      | C1 050 16  | MAYO SCISSORS STRAIGHT          | Class I    | Reusable  |
| 18      | C1 051 16  | MAYO SCISSORS CURVED            | Class I    | Reusable  |



|    |           |                                               |         |          |
|----|-----------|-----------------------------------------------|---------|----------|
| 19 | C1 051 18 | MAYO SCISSORS CURVED                          | Class I | Reusable |
| 20 | C1 060 10 | IRIS SCISSORS STRAIGHT                        | Class I | Reusable |
| 21 | C1 060 11 | IRIS SCISSORS STRAIGHT                        | Class I | Reusable |
| 22 | C1 061 10 | IRIS SCISSORS CURVED                          | Class I | Reusable |
| 23 | C1 061 11 | IRIS SCISSORS CURVED                          | Class I | Reusable |
| 24 | C1 110 10 | NAILS SCISSORS STRAIGHT                       | Class I | Reusable |
| 25 | C1 111 10 | NAILS SCISSORS CURVED                         | Class I | Reusable |
| 26 | C1 300 14 | DISSECTING FORCEPS                            | Class I | Reusable |
| 27 | C1 430 14 | TROELSCH FORCEPS WITHOUT TEETH                | Class I | Reusable |
| 28 | C1 432 14 | TROELSCH FORCEPS WITH TEETH                   | Class I | Reusable |
| 29 | C1 500 09 | FEILCHENFELD FORCEPS                          | Class I | Reusable |
| 30 | C2 000 14 | ROCHESTER PEAN FORCEPS STRAIGHT WITHOUT TEETH | Class I | Reusable |
| 31 | C2 000 16 | ROCHESTER PEAN FORCEPS STRAIGHT WITHOUT TEETH | Class I | Reusable |
| 32 | C2 010 14 | MURPHY PEAN FORCEPS                           | Class I | Reusable |
| 33 | C2 050 14 | ROCHESTER PEAN FORCEPS STRAIGHT WITH TEETH    | Class I | Reusable |
| 34 | C2 050 16 | ROCHESTER PEAN FORCEPS STRAIGHT WITH TEETH    | Class I | Reusable |
| 35 | C2 051 14 | ROCHESTER PEAN FORCEPS CURVED WITHOUT TEETH   | Class I | Reusable |
| 36 | C2 051 16 | ROCHESTER PEAN FORCEPS CURVED WITHOUT TEETH   | Class I | Reusable |
| 37 | C2 053 14 | ROCHESTER PEAN FORCEPS CURVED WITH TEETH      | Class I | Reusable |
| 38 | C2 053 16 | ROCHESTER PEAN FORCEPS CURVED WITH TEETH      | Class I | Reusable |
| 39 | C2 070 09 | HARTMANN FORCEPS STRAIGHT WITHOUT TEETH       | Class I | Reusable |
| 40 | C2 080 12 | HALSTEAD FORCEPS STRAIGHT WITHOUT TEETH       | Class I | Reusable |
| 41 | C2 081 12 | HALSTEAD FORCEPS CURVED WITHOUT TEETH         | Class I | Reusable |
| 42 | C2 082 12 | HALSTEAD FORCEPS STRAIGHT WITH TEETH          | Class I | Reusable |
| 43 | C2 083 12 | HALSTEAD FORCEPS CURVED WITH TEETH            | Class I | Reusable |
| 44 | C2 090 15 | LERICHE FORCEPS STRAIGHT WITHOUT TEETH        | Class I | Reusable |
| 45 | C2 091 15 | LERICHE FORCEPS CURVED WITHOUT TEETH          | Class I | Reusable |
| 46 | C2 092 15 | LERICHE FORCEPS STRAIGHT WITH TEETH           | Class I | Reusable |
| 47 | C2 093 15 | LERICHE FORCEPS CURVED WITH TEETH             | Class I | Reusable |
| 48 | C2 096 14 | KELLY FORCEPS STRAIGHT                        | Class I | Reusable |
| 49 | C2 096 16 | KELLY FORCEPS STRAIGHT                        | Class I | Reusable |
| 50 | C2 096 18 | KELLY FORCEPS STRAIGHT                        | Class I | Reusable |
| 51 | C2 097 14 | KELLY FORCEPS CURVED                          | Class I | Reusable |
| 52 | C2 097 16 | KELLY FORCEPS CURVED                          | Class I | Reusable |

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|----|-----------|-----------------------------------------|---------|----------|
| 53 | C2 228 18 | DOYEN INTESTINAL CLAMP FORCEPS STRAIGHT | Class I | Reusable |
| 54 | C2 229 18 | DOYEN INTESTINAL CLAMP FORCEPS CURVED   | Class I | Reusable |
| 55 | C2 240 14 | CRILE FORCEPS STRAIGHT                  | Class I | Reusable |
| 56 | C2 241 14 | CRILE FORCEPS CURVED                    | Class I | Reusable |
| 57 | C2 250 13 | TERRIER FORCEPS                         | Class I | Reusable |
| 58 | C2 300 00 | ADSON FORCEPS WITHOUT TEETH             | Class I | Reusable |
| 59 | C2 302 00 | ADSON FORCEPS WITH TEETH                | Class I | Reusable |
| 60 | C2 400 13 | MICHEL DOUBLE USE FORCEPS               | Class I | Reusable |
| 61 | C3 010 16 | MAYO HEGAR NEEDLE HOLDER                | Class I | Reusable |
| 62 | C3 030 14 | MATHIEU NEEDLE HOLDER                   | Class I | Reusable |
| 63 | C3 030 17 | MATHIEU NEEDLE HOLDER                   | Class I | Reusable |
| 64 | C3 035 13 | CRILE-WOOD NEEDLE HOLDER                | Class I | Reusable |
| 65 | C3 035 15 | CRILE-WOOD NEEDLE HOLDER                | Class I | Reusable |
| 66 | CV BM2 99 | GILLIES NEEDLE HOLDER                   | Class I | Reusable |

The manufactured products meet the essential requirement of Directive No. 93/42/EEC as amended by 2007/47/EC for Class I Surgical and Dental Instruments (Single-use, Reusable, Non-sterile and non-powered). We prepare and maintain technical documentation for each device as required by Annex- VII of the directive 93/42/EEC as amended by 2007/47/EC. We shall maintain these documentations for 5 years from the date of their production. The technical documentation can be made available to the competent authority on demand.

We further declare that we have designated the person responsible for marketing our above stated devices. Detail of the designated person responsible for marketing (Authorized Representative) is asunder:

#### IBC-Sweden

14564 Norsborg, Stockholm,  
Sweden  
eurep@ibcs sweden.eu

IBC Sweden has registered place of business in Sweden. He is also already registered with Swedish Medical Products Agency – Lakemedelsverket.

Date of issue: 10/05/2021

Authorized Name & Designation:

Place of issue: Sialkot-Pakistan

Akif Abbas (Mr.)

Managing Partner

Authorized Signature & Company Stamp:

**ZIANA INDUSTRIES**  
  
MG. PARTNER

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