

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
67	C1 400 14	DISSECTING FORCEPS WITH TEETH	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

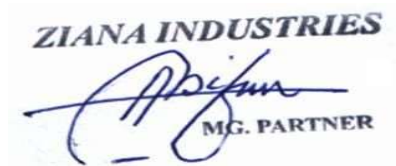
Authorized Name & Designation:

Place of issue: Sialkot-Pakistan

Akif Abbas (Mr.)

Managing Partner

Authorized Signature & Company Stamp:



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