

DECLARATION OF CONFORMITY

DOC# ZI/GEM/240111/786-5

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Ziana Industries

Islam Nagar Road, Pacca Garh,
Sialkot-51310, Pakistan.

Tel: +92 52 4261491 / 4265795

SRN # PK-MF-000011900

Email: sales@zianaindustries.com

Web: www.zianaindustries.com

Hereby declares that the appointed Authorized EU Representative

IBC-Sweden

14550 Norsborg,
Stockholm, Sweden

SRN # SE-AR-000001625

Email: eurep@ibcs sweden.eu

We hereby declare that the EC declaration of conformity is issued under the sole responsibility of the Ziana Industries, as per Annex II, Article 19 and Annex IV and tends to meet the essential and applicable requirements as per Annex IV under Regulation (EU) 2017/745. Medical Devices attached in Annex A are in conformity with the MDR 2017/745 and relevant harmonized standards and the relevant parts of applicable standards of Official Journal of the European Union, are applied where applicable and presumed to be in conformity with the requirements of "Risk class I" of the device in accordance with the rules set out in Annex VIII covered by those standards or parts thereof.

The products manufactured are provided in Annex A of this EC Declaration of conformity. The products declared in Annex A are in compliance to applicable standards and or are harmonized by EU Medical Device Regulation 2017/745. The traceability of the device covered by the EU declaration of conformity are in compliance where appropriate (Quality Management System and UDI protocols, as well as its intended purpose.

We also declare; Products mentioned in Annex A of this declaration are in conformity with applicable general safety and performance requirements given in Annex I of MDR 2017/745 under the conditions of the intended use of the device, Documents will be presented upon request to competent authority, the indicated therein, Ziana Industries, will provide that technical documentation and all applicable regulatory documents in its entirety and summary thereof.

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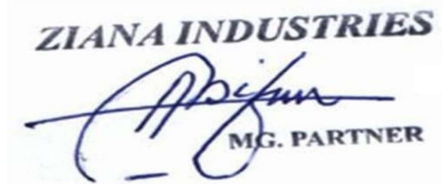
MG. PARTNER



The products manufactured are Class I (Non-Active, Non-Sterile, Non-Measuring and Non-Invasive), lower risk products in line with Annex VIII;

The Basic UDI-DI as referred to in Part C of Annex VI had been established in reference to product in Annex A as per information to be submitted upon the registration of Devices and Economic Operators in accordance with articles 28, 29 and 31.

We further declare that we have designated the person responsible for marketing our above stated devices.



ZIANA INDUSTRIES
MG. PARTNER

Authorized Name & Designation:
Akif Abbas Malik (Partner)

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 (Non-Active, Non-Sterile, Non-Measuring & Non-Invasive) medical devices and variant of product groups manufactured are as under:

Annex A

Sr #	Article #	Product Description	Sizes	Group Name	Basic UDI-DI
1	28 400 08	LARYNGEAL MIRROR, K 00	8MM	Laryngeal Mirror	896110270ZI0707LM900494L
2	28 400 10	LARYNGEAL MIRROR, K 0	10MM	Laryngeal Mirror	896110270ZI0707LM900494L
3	28 400 12	LARYNGEAL MIRROR, K 1	12MM	Laryngeal Mirror	896110270ZI0707LM900494L
4	28 400 14	LARYNGEAL MIRROR, K 2	14MM	Laryngeal Mirror	896110270ZI0707LM900494L
5	28 400 16	LARYNGEAL MIRROR, K 3	16MM	Laryngeal Mirror	896110270ZI0707LM900494L
6	28 400 18	LARYNGEAL MIRROR, K 4	18MM	Laryngeal Mirror	896110270ZI0707LM900494L
7	28 400 20	LARYNGEAL MIRROR, K 5	20MM	Laryngeal Mirror	896110270ZI0707LM900494L
8	28 400 22	LARYNGEAL MIRROR, K 6	22MM	Laryngeal Mirror	896110270ZI0707LM900494L
9	28 400 24	LARYNGEAL MIRROR, K 7	24MM	Laryngeal Mirror	896110270ZI0707LM900494L
10	28 400 26	LARYNGEAL MIRROR, K 8	26MM	Laryngeal Mirror	896110270ZI0707LM900494L
11	28 400 28	LARYNGEAL MIRROR, K 9	28MM	Laryngeal Mirror	896110270ZI0707LM900494L
12	28 400 30	LARYNGEAL MIRROR, K 10	30MM	Laryngeal Mirror	896110270ZI0707LM900494L
13	28 401 00	HANDLE WITH SCREW FOR MIRRORS		Laryngeal Mirror	896110270ZI0707LM900494L
14	29 200 28	HARTMANN TUNING FORK C128	25CM	Tunning Fork	896110270ZI0707TF900745Y
15	29 200 29	HARTMANN TUNING FORK WITH WEIGHT C128	17CM	Tunning Fork	896110270ZI0707TF900745Y
16	29 200 56	HARTMANN TUNING FORK C256	17.6CM	Tunning Fork	896110270ZI0707TF900745Y
17	29 200 57	HARTMANN TUNING FORK WITH WEIGHT C256	13.2CM	Tunning Fork	896110270ZI0707TF900745Y
18	29 200 64	NEUROLOGICAL TUNING FORK 64HZ		Tunning Fork	896110270ZI0707TF900745Y
19	29 205 12	HARTMANN TUNING FORK C512	16.5CM	Tunning Fork	896110270ZI0707TF900745Y
20	29 210 24	HARTMANN TUNING FORK C1024	15.3CM	Tunning Fork	896110270ZI0707TF900745Y
21	33 430 00	EYE MAGNET SIMPLE		Eye Magnet	896110270ZI0707EM90075YT
22	33 450 00	EYE MAGNET WITH MAGNIFYING GLASS		Eye Magnet	896110270ZI0707EM90075YT
23	33 600 00	TICK TWEEZER	8.5CM	Tweezer/Forceps	896110270ZI0707DT900042H
24	36 001 14	PROBE WITH KNOB	14CM	Probe	896110270ZI0707UP90076AP
25	36 002 14	PROBE WITH KNOB DOUBLE	14CM	Probe	896110270ZI0707UP90076AP
26	36 052 00	PROBE WITH THREAD	18CM	Probe	896110270ZI0707UP90076AP
27	41 581 00	BABINSKY REFLEX HAMMER STANDARD		Hammer	896110270ZI0707HM9003627
28	41 581 10	VERNON REFLEX HAMMER		Hammer	896110270ZI0707HM9003627

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29	41 581 20	BUCK REFLEX HAMMER	19CM	Hammer	896110270ZI0707HM9003627
30	41 581 30	TAYLOR REFLEX HAMMER	19CM	Hammer	896110270ZI0707HM9003627
31	43 960 00	PINARD STETHOSCOPE IN WOOD		Stethoscope	896110270ZI0707ST90077BB
32	43 960 10	PINARD STETHOSCOPE IN ALUMINIUM		Stethoscope	896110270ZI0707ST90077BB
33	47 310 00	STILLE PLASTER SHEARS	37CM	Plaster Shear	896110270ZI0707PS900789D
34	47 310 21	PLASTER SHEARS	21CM	Plaster Shear	896110270ZI0707PS900789D
35	47 310 23	BRUN PLASTER SHEARS	23CM	Plaster Shear	896110270ZI0707PS900789D
36	47 320 00	HENNING PLASTER SPREADER	28CM	Plaster Spreader	896110270ZI0707PS900869C
37	C1 100 14	LISTER SCISSORS	14CM	Scissors	896110270ZI0707SC900323Q
38	C1 100 16	LISTER SCISSORS	16CM	Scissors	896110270ZI0707SC900323Q
39	C1 100 18	LISTER SCISSORS	18CM	Scissors	896110270ZI0707SC900323Q
40	C1 150 11	SPENCER SCISSORS	11CM	Scissors	896110270ZI0707SC900323Q
41	C1 150 13	SPENCER SCISSORS	13CM	Scissors	896110270ZI0707SC900323Q
42	C1 165 16	KELLY SCISSORS STRAIGHT	16CM	Scissors	896110270ZI0707SC900323Q
43	29 102 40	UTILITY SCISSORS, PLASTIC HANDLE (RED COLOR)	18.5CM	Scissors	896110270ZI0707SC900323Q
44	29 102 41	UTILITY SCISSORS, PLASTIC HANDLE (BLUE COLOR)	18.5CM	Scissors	896110270ZI0707SC900323Q
45	29 102 42	UTILITY SCISSORS, PLASTIC HANDLE (YELLOW COLOR)	18.5CM	Scissors	896110270ZI0707SC900323Q
46	29 102 45	UTILITY SCISSORS, PLASTIC HANDLE (BLACK COLOR)	18.5CM	Scissors	896110270ZI0707SC900323Q
47	C1 200 03	SCALPEL HANDLE	#3	Scalpel Handle	896110270ZI0707SH900305M
48	C1 200 04	SCALPEL HANDLE	#4	Scalpel Handle	896110270ZI0707SH900305M
49	C1 200 50	DIRECTOR & TONGUE TIE	14CM	Director	896110270ZI0707DP90002YN
50	C1 440 15	LONDON COLLEGE TWEEZER	15CM	Tweezer/Forceps	896110270ZI0707DT900042H
51	C1 450 12	SEMKN DISSECTION FORCEPS	12CM	Forceps	896110270ZI0707DF90017UZ
52	C2 100 24	MAIR POLYPUS FRENCH FORCEPS STRAIGHT	24CM	Forceps	896110270ZI0707DF90017UZ
53	C2 110 24	CHERON FORCEPS	24CM	Forceps	896110270ZI0707DF90017UZ
54	C2 200 11	BACKHAUS FORCEPS	11CM	Forceps	896110270ZI0707DF90017UZ
55	C2 200 13	BACKHAUS FORCEPS	13CM	Forceps	896110270ZI0707DF90017UZ
56	C2 220 09	JONES TOWEL FORCEPS	9CM	Forceps	896110270ZI0707DF90017UZ
57	C2 260 15	MAGILL FORCEPS	15CM	Forceps	896110270ZI0707DF90017UZ
58	C2 260 20	MAGILL FORCEPS	20CM	Forceps	896110270ZI0707DF90017UZ
59	C2 260 24	MAGILL FORCEPS	24CM	Forceps	896110270ZI0707DF90017UZ
60	C2 265 13	HARTMANN EAR POLYPUS FORCEPS	13CM	Forceps	896110270ZI0707DF90017UZ
61	C2 280 24	POZZI FORCEPS	24CM	Forceps	896110270ZI0707DF90017UZ
62	C2 290 24	FOERSTER FORCEPS STRAIGHT	24CM	Forceps	896110270ZI0707DF90017UZ

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63	C2 291 24	FOERSTER FORCEPS CURVED	24CM	Forceps	896110270ZI0707DF90017UZ
64	C1 500 11	FEILCHENFELD SPLINTER FORCEPS 11CM		Forceps	896110270ZI0707DF90017UZ
65	C4 107 01	BILLEAU LOOP, SMALL	1.5x3MM	Loop	896110270ZI0707EL90080Y7
66	C4 107 02	BILLEAU LOOP, MEDIUM	2x4MM	Loop	896110270ZI0707EL90080Y7
67	C4 107 03	BILLEAU LOOP, LARGE	3x5MM	Loop	896110270ZI0707EL90080Y7
68	C4 200 13	SNELLEN LOOP	13.5CM	Loop	896110270ZI0707EL90080Y7
69	C5 200 08	BISHOP HARMANN FORCEPS WITHOUT TEETH	8CM	Tweezer/Forceps	896110270ZI0707DT900042H
70	C5 420 16	BRUCELLE MIRIAM FORCEPS	16CM	Tweezer/Forceps	896110270ZI0707DT900042H
71	C5 500 02	VACHER NASAL SPECULUM	ADULTS	Nasal Speculum	896110270ZI0707NS9004882
72	C8 020 01	CUSCO SPECULUM, SMALL	75 x 32 MM	Vaginal Speculum	896110270ZI0707VS90040BS
73	C8 020 02	CUSCO SPECULUM, MEDIUM	85 X 35MM	Vaginal Speculum	896110270ZI0707VS90040BS
74	C8 020 03	CUSCO SPECULUM, LARGE	100X37MM	Vaginal Speculum	896110270ZI0707VS90040BS
75	C8 021 25	COLLIN SPECULUM	25 X 110MM	Vaginal Speculum	896110270ZI0707VS90040BS
76	C8 021 30	COLLIN SPECULUM	30 X 110MM	Vaginal Speculum	896110270ZI0707VS90040BS
77	C8 021 35	COLLIN SPECULUM	35 X 110MM	Vaginal Speculum	896110270ZI0707VS90040BS
78	C8 021 38	COLLIN SPECULUM	38X120MM	Vaginal Speculum	896110270ZI0707VS90040BS
79	C8 021 40	COLLIN SPECULUM	40 X 120MM	Vaginal Speculum	896110270ZI0707VS90040BS

For and on behalf of Ziana Industries

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Applicable Standards

Standards	Description
ISO 14971	Medical devices-Application of risk management to medical Devices
Regulation (EU) 2017/745	Medical Device Regulation (MDR)
EN ISO 13485: 2016	Medical devices-Quality management systems-Requirements for regulatory purposes.
ISO 15223-2:2010	Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied - Part 2: Symbol
ISO 15223-1	Graphical Symbols for Use in the Labeling of 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

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