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ZIANA INDUSTRIES

EC DECLARATION OF CONFORMITY

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ZIANA INDUSTRIES
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Hereby declares that the appointed Authorized EU Representative
IBC-Sweden - 14564 Norsborg, Stockholm, Sweden.

This declaration is issued under the sole responsibility of the manufacturer and tends to meet the essential and applicable requirements as per Annex IV under EU MDR 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 and given in Annex A of this declaration manufactured are in accordance with applicable requirements of MDR 2017/745 and issued EC Declaration of conformity. The products declared 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, as well as its intended purpose.

We also declare; documents will be presented upon request, the indicated therein, Ziana Industries will provide that technical documentation in its entirety and or in summary thereof.
The product manufactured are Reusable (Non-Sterilized) is in class I as low risk product, lower risk products in line with Annex VIII; The product referred are developed with due care in lieu of technical documentation referred to in Annexes II and III.

To keep the technical documentation, the EU declaration of conformity and relevant certificates, including any amendments and supplements, issued in accordance with Article 56, available for a period of at least 05 years after the last device covered by the EU declaration of conformity has been placed on the market.

Sign and Stamp

Annex A
Product List

Declares that products list has been classified as Medical Devices (Class I) inclusive of mentioned product variants is in conformity with the essential requirements, provisions of Medical Device Regulation 2017/745 and applicable regulatory requirements.

Sr. No.	Item Codes	Item Description	SIZES	TRADE NAME CODE	BASIC UDI-DI
1	28 400 08	LARYNGEAL MIRROR, K 00	8MM	Laryngeal Mirrors and Handles	89611027011015
2	28 400 10	LARYNGEAL MIRROR, K 0	10MM		
3	28 400 12	LARYNGEAL MIRROR, K 1	12MM		
4	28 400 14	LARYNGEAL MIRROR, K 2	14MM		
5	28 400 16	LARYNGEAL MIRROR, K 3	16MM		
6	28 400 18	LARYNGEAL MIRROR, K 4	18MM		
7	28 400 20	LARYNGEAL MIRROR, K 5	20MM		
8	28 400 22	LARYNGEAL MIRROR, K 6	22MM		
9	28 400 24	LARYNGEAL MIRROR, K 7	24MM		
10	28 400 26	LARYNGEAL MIRROR, K 8	26MM		
11	28 400 28	LARYNGEAL MIRROR, K 9	28MM		
12	28 400 30	LARYNGEAL MIRROR, K 10	30MM		
13	28 401 00	HANDLE WITH SCREW FOR MIRRORS			
14	29 200 28	HARTMANN TUNING FORK C128	25CM	Tuning Fork	89611027012012
15	29 200 29	HARTMANN TUNING FORK WITH WEIGHT C128	17CM		
16	29 200 56	HARTMANN TUNING FORK C256	17.6CM		
17	29 200 57	HARTMANN TUNING FORK WITH WEIGHT C256	13.2CM		
18	29 200 64	NEUROLOGICAL TUNING FORK 64HZ			
19	29 205 12	HARTMANN TUNING FORK C512	16.5CM		
20	29 210 24	HARTMANN TUNING FORK C1024	15.3CM		
21	33 430 00	EYE MAGNET SIMPLE		Eye Magnet /with mirrors/Magnifying glass	89611027016010
22	33 450 00	EYE MAGNET WITH MAGNIFYING GLASS			

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23	33 600 00	TICK TWEEZER	8.5CM	Tweezers	89611027013019
24	36 001 14	PROBE WITH KNOB	14CM	Probes	89611027010018
25	36 002 14	PROBE WITH KNOB DOUBLE	14CM		
26	36 052 00	PROBE WITH THREAD	18CM		
27	41 581 00	BABINSKY REFLEX HAMMER STANDARD		Percussion Hammers	89611027014016
28	41 581 10	VERNON REFLEX HAMMER			
29	41 581 20	BUCK REFLEX HAMMER	19CM		
30	41 581 30	TAYLOR REFLEX HAMMER	19CM		
31	43 960 00	PINARD STETHOSCOPE IN WOOD		Stethoscope	89611027015013
32	43 960 10	PINARD STETHOSCOPE IN ALUMINIUM			
33	47 310 00	STILLE PLASTER SHEARS	37CM	Shears	89611027017017
34	47 310 21	PLASTER SHEARS	21CM		
35	47 310 23	BRUN PLASTER SHEARS	23CM		
36	47 320 00	HENNING PLASTER SPREADER	28CM		
37	C1 100 14	LISTER SCISSORS	14CM	Scissors	89611027002013
38	C1 100 16	LISTER SCISSORS	16CM		
39	C1 100 18	LISTER SCISSORS	18CM		
40	C1 150 11	SPENCER SCISSORS	11CM		
41	C1 150 13	SPENCER SCISSORS	13CM		
42	C1 165 16	KELLY SCISSORS STRAIGHT	16CM		
43	C1 200 03	SCALPEL HANDLE # 3		Scalpel Handles	89611027018014
44	C1 200 04	SCALPEL HANDLE # 4			
45	C1 200 50	DIRECTOR & TONGUE TIE	14CM	Director & Tongue Tie	89611027019011
46	C1 440 15	LONDON COLLEGE TWEEZER	15CM	Tweezers	89611027013019
47	C1 450 12	SEMKIN DISSECTION FORCEPS	12CM		

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48	C2 100 24	MAIR POLYPUS FRENCH FORCEPS STRAIGHT	24CM	Forceps	89611027003010
49	C2 110 24	CHERON FORCEPS	24CM		
50	C2 200 11	BACKHAUS FORCEPS	11CM		
51	C2 200 13	BACKHAUS FORCEPS	13CM		
52	C2 220 09	JONES TOWEL FORCEPS	9CM		
53	C2 260 15	MAGILL FORCEPS	15CM		
54	C2 260 20	MAGILL FORCEPS	20CM		
55	C2 260 24	MAGILL FORCEPS	24CM		
56	C2 265 13	HARTMANN EAR POLYPUS FORCEPS	13CM		
57	C2 280 24	POZZI FORCEPS	24CM		
58	C2 290 24	FOERSTER FORCEPS STRAIGHT	24CM		
59	C2 291 24	FOERSTER FORCEPS CURVED	24CM		
60	C4 107 01	BILLEAU LOOP, SMALL	1.5x3MM	Ear Loops	89611027021014
61	C4 107 02	BILLEAU LOOP, MEDIUM	2x4MM		
62	C4 107 03	BILLEAU LOOP, LARGE	3x5MM		
63	C4 200 13	SNELLEN LOOP	13.5CM		
64	C5 200 08	BISHOP HARMANN FORCEPS WITHOUT TEETH	8CM	Tweezers	89611027013019
65	C5 420 16	BRUCELLE MIRIAM FORCEPS	16CM		
66	C5 500 02	VACHER NASAL SPECULUM	ADULTS	Nasal Speculum	89611027020017
67	C8 020 01	CUSCO SPECULUM, SMALL	75 x 32 MM	Vaginal Speculums	89611027020024
68	C8 020 02	CUSCO SPECULUM, MEDIUM	85 X 35MM		
69	C8 021 25	COLLIN SPECULUM	25 X 110MM		
70	C8 021 30	COLLIN SPECULUM	30 X 110MM		
71	C8 021 35	COLLIN SPECULUM	35 X 110MM		
72	C8 021 38	COLLIN SPECULUM	38X120MM		
73	C8 021 40	COLLIN SPECULUM	40 X 120MM		

For and on behalf of Ziana Industries

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Annex B

The products mentioned in Annex A of this declaration are hereby declared in conformity with applicable harmonized standard mentioned below.

Standards	Description
Medical devices-Application of risk management to medical Devices	ISO 14971
Medical Device Regulation (MDR)	Regulation (EU) 2017/745
Medical devices-Quality management systems-Requirements for regulatory purposes.	EN ISO 13485: 2016
Biological evaluation of medical devices-Part 1: Evaluation and testing	ISO 10993-1
Biological evaluation of medical devices -Part 2: Animal welfare requirements	ISO10993-2
Biological evaluation of medical Devices-Part 3: Tests for genotoxicity, carcinogenicity and reproductive toxicity	EN ISO10993-3
Medical devices -- Symbols to be used with medical device labels, labelling, and information to be supplied - Part 2: Symbol	ISO 15223-2:2010
Graphical Symbols for Use in the Labeling of Medical Devices	ISO 15223-1
Guide line for authorized representatives	MEDDEV 2.5. /10
Medical device classification	MEDDEV 2.4/1
Evaluation of clinical data- guide for manufacturer and notified bodies	MEDDEV 2.7.1 Appendix-1
Medical device vigilance system	MEDDEV 2.12.1
Standard Specification for Stainless Steel Billet, Bar, and Wire for Surgical Instruments	ASTM-F899
Surgical Instruments – Metallic Materials – Part 1: Stainless Steel	ISO 7153-1
Sterilization of Health care products	ISO 17665-1

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