



Certificate of Compliance

We hereby declare that the technical file of product complied with the requirement of
Medical devices (93/42/EEC) Directive

LAKSHAYA ENTERPRISE

SHOP NO.-09, RAJOURI APPARMENT MARKET, NEAR
GOVERNMENT PRESS, MAYAPURI, WEST DELHI -110064, INDIA

Has been assessed by optimum certifications Inc. and found to be
in Compliance with meeting the requirements of:

Directive (93/42/EEC) Medical Device
More Details as per Appendix –I TO XII

The certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to Medical devices (93/42/EEC) Directive .

This certificate issued under the following conditions:

1. It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type examination procedures, if requested
2. The certificate remains valid until the manufacturing conditions or the quality system are changed
3. The certificate validity is conditioned by positive results of surveillance audits
4. After fulfilling relevant EEC legislation, the manufacturer shall affix to each device, of the referenced models The CE mark as shown above can be used under the responsibility of the manufacturer after completion of an EEC Declaration of conformity and compliance with all relevant EEC Directives. The statement is based on a single evaluation of one sample of above mentioned product. not imply an assessment of the whole production

Date of Certification: 09th October 2021

1st Surveillance Due: 08th October 2022

2nd Surveillance Due: 08th October 2023

Certificate Expiry: 08th October 2024

Subject To The Company Maintaining Its
system To The Required Standard)

Certificate Number: CE/21N1805

Validity of this certificate can be verified at www.ocicert.com

Authorised Signatory



Optimum Certifications Inc.

Validity of This Certificate is Successful Annual Surveillance Audit To Be Done.
This Certificate is The Property of Optimum Certifications Inc. Shall Be Returned Immediately Upon Request,
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Certificate of Compliance

APPENDIX-I

The Appendix shall be an integral part of the certificate. All expressions and terms defined or used in the certificate shall have the same meaning in this addendum, unless the context clearly required otherwise

This certificate referred to above covers the following Products:

Sr. No.	Product	Model/Variants to be certified	Rule as Per MDD 93/42/EEC	class
Product Group 1- Hospital Medical Furniture				
1	Hospital Bed	ICU Bed Electric Multi Function	Rule 1	Class I
		ICU Bed Non Electric Multi Function	Rule 1	Class I
		Mechanical Fowler Bed for adult and Children,	Rule 1	Class I
		Semi Fowler Bed for Adult and Children	Rule 1	Class I
		General/Standard Bed,	Rule 1	Class I
		Orthopedic Bed	Rule 1	Class I
		Infant Bed/Infant Cot/ Infant	Rule 1	Class I
		Examination Table Electric / Non Electric,	Rule 1	Class I
2	Delivery/ Gynecological Tables/Beds	Delivery Bed/ Gynecological Bed	Rule 1	Class I
3	Ward Furniture	IV Pole Saline Stand	Rule 1	Class I
		Blood Donor Chair	Rule 1	Class I
		Waiting Chairs & Benches	Rule 1	Class I
		Medical Cabinets Cupboards	Rule 1	Class I
		Bedside lockers	Rule 1	Class I
		Medicine Trolley Treatment Trolley	Rule 1	Class I

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APPENDIX-II

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Sr. No.	Product	Model/Variants to be certified	Rule as Per MDD 93/42/EEC	class
Product Group 1- Hospital Medical Furniture				
3	Ward Furniture	Mayo Type Trolley	Rule 1	Class I
		Bedside Screen	Rule 1	Class I
		Foot Stool	Rule 1	Class I
		Bowl Stand	Rule 1	Class I
		Instrument Cabinet	Rule 1	Class I
		Medicine Cabinet	Rule 1	Class I
4	Stretcher	Patient Transfer Stretcher	Rule 1	Class I
		Single Fold Stretcher	Rule 1	Class I
		Double Fold Stretcher	Rule 1	Class I
		Stretcher Three Fold Stretcher Four Fold	Rule 1	Class I
5	Mobility aids	Wheel Chairs	Rule 1	Class I
		Walking Sticks	Rule 1	Class I
		Crutches	Rule 1	Class I
		Walker	Rule 1	Class I
		Commode Chair	Rule 1	Class I

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This certificate referred to above covers the following Products:

Sr. No.	Product	Model/Variants to be certified	Rule as Per MDD 93/42/EEC	class
Product Group 2- Hospital Holloware				
6	Hospital Holloware	Urinals (Male & Female)	Rule 1	Class I
		Spittoons/Sputum Mugs (Stainless Steel / Plastic)	Rule 1	Class I
		Douche Cans (Stainless Steel /Plastic)	Rule 1	Class I
		Bed Pans (Stainless Steel / Plastic)	Rule 1	Class I
		Buckets (Stainless Steel / Plastic)	Rule 1	Class I
		Bowls & Basins (Stainless Steel/Plastic)	Rule 1	Class I
		Wire Mesh Trays, Sterilization: Cassette, Cidex Tray, Sterilizing	Rule 1	Class I
		Dressing trays Stainless Steel	Rule 1	Class I
		Kidney Trays (Stainless Steel/Plastic)	Rule 1	Class I
		Jar (Stainless Steel/Plastic)	Rule 1	Class I
		Thermometer Jar, Forceps Jar,	Rule 1	Class I
		Medicine Measure (Stainless Steel/ Plastic)	Rule 1	Class I
		Measuring Spoon (Stainless Steel/Plastic)	Rule 1	Class I
		Jug Measuring (Stainless Steel/ Plastic)	Rule 1	Class I

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APPENDIX-IV

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This certificate referred to above covers the following Products:

Sr. No.	Product	Model/Variants to be certified	Rule as Per MDD 93/42/EEC	class
Product Group 3- OT Equipment				
7	OT Tables	Operation Theatre Table - Microprocessor Controlled, Electrically Operated, Electrohydraulic Operated, Electric Hydraulic Operated, Hydraulically Operated, Mechanical Operated & Electro Mechanical operated.	Rule 1	Class I
8	OT lights	Operation Theatre Light Mobile	Rule 1	Class I
		Operation Theatre Light Ceiling Mounted	Rule 1	Class I
		Operation Theatre Light Wall Mounted	Rule 1	Class I
Product Group 4-Surgical Medical Disposables				
9	Disposable Non-Woven	Surgical gown. Nurse Gown. Scrub Suit, Lab Coat, Face Mask Non Woven, Surgeon Cap, Nurse Cap. Shoe Cover, Boot Cover, Over Sleeves, Apron Non-Woven. Disposable Apron PE, Dental apron, Cover all.	Rule 1	Class I

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APPENDIX-V

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This certificate referred to above covers the following Products:

Sr. No.	Product	Model/Variants to be certified	Rule as Per MDD 93/42/EEC	class
Product Group 4-Surgical Medical Disposables				
10	Reusable	Surgical gown, Nurse gown, Patient Gown, Baby Gown, Scrub suit, Nurse Maxi Lab Coat. Face Mask, Surgeon Cap. Apron Reusable PVC, Drape Sheet	Rule 1	Class I
11	Examination Gloves	Examination Gloves Latex. Non Sterile. Disposable	Rule 5	Class I
12	Breathing Exerciser		Rule 1	Class I
13	Oxygen Mask	Adult/Child	Rule 1	Class I
14	Body Bags		Rule 1	Class I
15	Nebulizer Mask		Rule 1	Class I
16	Tongue Depressor Disposable Wooden		Rule 1	Class I
17	Patient Identification Bands		Rule 1	Class I
18	Examination Gloves PE (LDPE/HDPE)-		Rule 1	Class I

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APPENDIX-VI

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This certificate referred to above covers the following Products:

Sr. No.	Product	Model/Variants to be certified	Rule as Per MDD 93/42/EEC	Class
Product Group 4-Surgical Medical Disposables				
19	Biohazard Garbage Bags		Rule 1	Class I
20	Safety Boxes Cardboard and PP		Rule 1	Class I
21	Intra Venous Catheter	I.V catheter with injection port and wings Size : 14, 16, 17, 18, 20, 22, 24 , 26 G	Rule 1	Class I
		I.V catheter with injection port and wings (transparent catheter) Size : 14, 16, 17, 18, 20, 22, 24 G	Rule 1	Class I
		I.V catheter without injection port, without wings Size : 14, 16, 18, 20, 22, 24, 26 G	Rule 1	Class I
		I.V with Safety advantage Size : 14, 16, 18, 20, 22, 24 G	Rule 1	Class I
		I.V catheter for neonates Size : 26 G	Rule 1	Class I
		I.V catheter for infants and neonates Size :24 G	Rule 1	Class I
		I.V catheter with an integrated three way stopcock Size : 16, 18, 20, 22 G	Rule 1	Class I

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Certificate of Compliance

APPENDIX-VII

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This certificate referred to above covers the following Products:

Sr. No.	Product	Model/Variants to be certified	Rule as Per MDD 93/42/EEC	Class
Product Group 4-Surgical Medical Disposables				
21	Intra Venous Catheter	I.V catheter without injection port Size : 14, 16, 18, 20, 22, 24, 26 G	Rule I	Class I
22	Three way stop cock		Rule I	Class I
23	I.V infusion set	I.V infusion set with airvent	Rule I	Class I
		I.V infusion set with airvent and Y-site	Rule I	Class I
		Intravenous infusions system with multiple stopcocks in line	Rule I	Class I
		I.V fluid infusion set with flow regulator	Rule I	Class I
		I.V fluid flow regulator extension set	Rule I	Class I
		Extension line with male and female ends	Rule I	Class I
		High pressure extension line	Rule I	Class I
24	Injection stopper		Rule I	Class I
25	Luer cap		Rule I	Class I

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APPENDIX-VIII

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This certificate referred to above covers the following Products:

Sr. No.	Product	Model/Variants to be certified	Rule as Per MDD 93/42/EEC	class
Product Group 4-Surgical Medical Disposables				
26	Percutaneous Sheath Introducer Set		Rule I	Class I
27	Haemodialysis kit		Rule I	Class I
28	A.V. fistula needle set		Rule I	Class I
29	Central venous catheter	Central venous catheter - single lumen	Rule I	Class I
		Central venous catheter - double lumen	Rule I	Class I
		Central venous catheter - triple lumen	Rule I	Class I
		Central venous catheter	Rule I	Class I
30	Epidural kit		Rule I	Class I
31	Suction catheter		Rule I	Class I
32	Spinal needle		Rule I	Class I
33	Guedel airway	Latex foley catheter	Rule I	Class I

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APPENDIX-IX

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This certificate referred to above covers the following Products:

Sr. No.	Product	Model/Variants to be certified	Rule as Per MDD 93/42/EEC	class
Product Group 4-Surgical Medical Disposables				
34	Tracheostomy tube		Rule I	Class I
35	Mucus extractor		Rule I	Class I
36	Infant feeding tube		Rule I	Class I
37	Ryle's tube		Rule I	Class I
38	Respiratory Exerciser (3 ball model)		Rule I	Class I
39	Laryngeal mask airway		Rule I	Class I
40	Connecting tube with yankaur handle		Rule I	Class I
41	Thoracic catheter		Rule I	Class I
42	Closed wound suction unit		Rule I	Class I
43	Nelaton catheter		Rule I	Class I
44	Foley catheter	Latex foley catheter	Rule I	Class I
		Silicon foley catheter	Rule I	Class I
45	Blood transfusion set		Rule I	Class I
46	Urine Bag		Rule I	Class I

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APPENDIX-X

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This certificate referred to above covers the following Products:

Sr. No.	Product	Model/Variants to be certified	Rule as Per MDD 93/42/EEC	Class
Product Group 5-Diagnostic Equipments and Products				
47	ENT SET		Rule 5	Class I
48	Sphygmomanometers Spares	Cuff/armband, for adult, with velcro type fasteners. Rubber Bulbs (inflating balls) - Oval Shape Rubber Bulbs (inflating balls) - Oblong Shape Rubber Bulbs (inflating balls) - Oval Shape Rubber Bulbs (inflating balls) - Oblong Shape Metal air control/valves	Rule 5	Class I

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APPENDIX-XI

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This certificate referred to above covers the following Products:

Sr. No.	Product	Model/Variants to be certified	Rule as Per MDD 93/42/EEC	Class
Product Group 5-Diagnostic Equipments and Products				
49	Otoscope and Ophthalmoscope Diagnostic Set		Rule 5	Class I
50	Stethoscopes and Spare Parts	Stethoscopes Dual Headed Stethoscopes Single Headed Stethoscope Tubes Stethoscope Pinard Foetal. Aluminum,Plastic	Rule 5	Class I
51	Armlet Bag		Rule 5	Class I

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This certificate referred to above covers the following Products:

Sr. No.	Product	Model/Variants to be certified	Rule as Per MDD 93/42/EEC	Class
Product Group 6- Laboratory Products				
52	Laboratory Products	Laboratory Plasticware	Rule 1	Class I
		Stop Watch	Rule 1	Class I
		Mechanical / Digital Timer	Rule 1	Class I
Product Group 7-Miscellaneous Surgical Medical Products				
53	Needle Syringe Destroyer	Needle Syringe Destroyer Electrical & Manual	Rule 1	Class I
54	Blanket Emergency	Child and Adult	Rule 1	Class I
55	Razor Razor Blades Razor single edge Surgical	Razor Double Edge Double Edge Razor blade	Rule 6	Class I
56	Safety Pins		Rule 1	Class I
57	Blanket Survival (Warming Foil)		Rule 1	Class I
58	Nail Brush		Rule 1	Class I
59	Crescent	2 ml Pack of 10	Rule 1	Class I
60	Solution for Nebulization	2 ml, 5 ml, 10 ml, 50 ml & 100 ml	Rule 1	Class I

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