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Certificate of Conformity

We confirm that the technical documentation for the below mentioned products (All Devices except Devices for Self-Testing and Annex II Devices) according to the Council Directive 98/79/EC

Sterlizers (Non Electric) & Formalin Chamber
(For Laboratory Use Only)

Manufactured by Company

SPEEDWAY SURGICAL CO.

A-67/5, G. T. KARNAL ROAD, INDUSTRIAL AREA, DELHI – 110 033, INDIA

complies with the applicable requirements of the Directive 98/79/EC (Annex II, Section 4 & 5).

Referring to the intended use, the Certification Body has conducted with successful results the review of the Manufacturer's Technical documentation of the certified product according to above mentioned Directive and appropriate Harmonized European Standards.

This Certificate is issued under the following conditions:

1. The Manufacturer's Technical Documentation, as required for 'All Devices except Devices for Self Testing and Annex II Devices', has been reviewed and found to comply with the requirements in Annex II, Section 4 & 5.
2. It applies only to the above mentioned In-vitro Devices/ Equipments.
3. The Manufacturer is obligated to assure conformity of all the In-vitro Devices/ Equipments of the respective model to the type assessed by the mean of this Certificate.
4. Any significant changes in the design or Process used to manufacture the Product, or revision to the Directives or standards referred above may require special audit by Eurotech Assessment and Certification Services Ltd. The product liability rests with the Manufacturer or his Representative in accordance with Council Directive.
5. After fulfilling the relevant EU Legislation Requirements, the Manufacturer shall affix to each Medical Device, CE Marking according to the following example:



Certificate No. : ET/IVDD/2019/1201

Issued On : August 25, 2014

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Valid Up To : May 25, 2024

Eurotech Assessment and Certification Services Ltd.

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Certificate of Conformity

We confirm that the Technical Documentation for the below mentioned Product (Medical Devices of the Class I) according to the Council Directive 93/42/EEC as amended by 2007/47/EC

Hospital Furniture, Hospital Hollowware, Surgical Instruments (Non-sterile), Ophthalmic Equipments, Eye OPD & O.T. Furniture & Miscellaneous Ophthalmic Products

(For detailed specifications, refer to Annexure of this Certificate, Pages 5)

Manufactured by Company

SPEEDWAY SURGICAL CO.

A-67/5, G. T. KARNAL ROAD, INDUSTRIAL AREA, DELHI – 110 033, INDIA

complies with the applicable requirements of the Directive 93/42/EEC as amended by 2007/47/EC.

Referring to the intended use, the Certification Body has conducted with successful results the review of the Manufacturer's Technical documentation of the certified product according to above mentioned Directive and appropriate Harmonized European Standards.

This Certificate is issued under the following conditions:

1. The Manufacturer's Technical Documentation, as required for Class I Devices, has been reviewed and found to comply with the requirements in Annex VII, Section 3.
2. It applies only to the above mentioned Medical Devices.
3. The Manufacturer is obligated to assure conformity of all the Medical Devices of the respective model to the type assessed by the mean of this Certificate.
4. Any significant changes in the Design or Process used to manufacture the Product, or revision to the Directives or standards referred above may require special audit by Eurotech Assessment and Certification Services Ltd. The Product liability rests with the Manufacturer or his Representative in accordance with Council Directive.
5. After fulfilling the relevant EU Legislation Requirements, the Manufacturer shall affix to each Medical Device, CE Marking according to the following example:



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Annexure to Certificate

No. ET/MDD/2019/1200

Issued for the Company:

SPEEDWAY SURGICAL CO.

A-67/5, G. T. KARNAL ROAD, INDUSTRIAL AREA, DELHI – 110 033, INDIA

List of the Medical Devices covered by the EC Certificate:

Product Group 1 – Hospital Furniture	
Product	Type of Models
Hospital Beds	Hospital, Movable Fully Fowler, Semi Fowler, Plain, Attendant Bed, ICU, Pediatric, Delivery
Tables	Examination, Over Bed, ENT
Trolleys	Medicines, Ward, Cylinder, Food & Linen, Instrument, Waste Handling, Dressing, Stretcher on Trolley, Emergency & Recovery
Stools	Attendant, Revolving and Patient
Lockers	Bed Side & Medicine
Stretchers	Folding Stretcher Single Fold (Canvas), Folding Stretcher Two Fold (Double Fold), Folding Stretcher Three Fold, Folding Stretcher Four Fold, Wheelchair cum Stretcher & Scoop Stretcher
Wheel chairs	Wheel Chair Folding, Electronic Wheel Chair, Invalid Wheel chair Folding & Fixed Deluxe, Powered Wheelchair & Manual Wheel chair
Foot Step	Single & Double
Saline Stand	Single & Double
Product Group 2 - Hospital Hollowware	
Fetal Scope	Plastic & Aluminum
Trays	Kidney, Instrument (with/ without Lid), Catheter, Mayo, Dental, Medicine, Instruments (Plastic & Stainless Steel)
Jars	Forceps, Dressing, Thermometer & Measuring
Bowls / Galipot	Lotion, Solution, Sponge & Wash
Bed Pan	Male & Female
Urinal Pot	Male & Female
Cup	Medicine, Iodine & Feeding
Dressing Drum	--
Instrument Box	--
Test Tube Stand	Plastic & Aluminum
Can	Douche & Enema
Basin	Stainless Steel & Plastic
Spirit Lamp	Stainless Steel, Aluminum & Brass

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List of the Medical Devices covered by the EC Certificate:

Product Group 2 – Hospital Hollowware	
Product	Type of Models
Spitton Mug	–
Funnel	–
Sterilizing Trays	–
Bucket	Stainless Steel & Aluminum
Waste/ Dust Bin	Stainless Steel & Plastic
Cheatele Forceps Jar	Stainless Steel
Product Group 3 - Surgical Instruments (Non-sterile)	
Speculum	Eye, Nasal, Aural, Vaginal
Retractors	Eye, Scleral, Orbital, Lid, Lachrymal, IRIS, Mastoid, Vaginal, Endocervical
Hooks & Manipulators	IOL, Lens, Nucleus, IRIS, Muscle, Lachrymal, Retinal, Intra-capsular, Tenotomy, Scleral, Fistula, Single, Double, Obstetrics, Skin
Nucleus Chopper/ Fragmentation	Cutter, Cracker, Splitter, Sustainer, Spatula, Bisector, Tri-sector, Y Shaped
Spatula / Depressor	Ptosis, Entropion, Nucleus, Lens, IRIS, Cyclodialysis, Keratoplasty, Retinal, Scleral, Tongue, Abdominal, Uterine
Knives	IRIS, Capsulotomy, Corneal, Keratoplasty, Cataract, Retinal, Ophthalmic, Lance Tip, MVR, Crescent
Rougine	Corneal, Foreign Body, Cutting, Round Body. Dissection, IRIS, Fascia
Spud	Corneal, Foreign Body, Cutting, Round Body. Dissection, IRIS, Fascia
Repository	Corneal, Foreign Body, Cutting, Round Body, Dissection, IRIS, Fascia
Scoops, Spoons, Curettes, Reusable Cautery's	Evisceration, Enucleation, Chalazion, Capsule, Biopsy, Ovum, Suction, Uterine, S. S.
Dissectors	Rhinology, Aspirating, Mono-polar Aspirating, Tonsillectomy, Lang, Dastoor
Elevators	Lachrymal, Periosteal, Uterine, Middle Ear, Stapedectomy, Bayonet Shaped, Ear Drum, Rhinology
Dilators	Punctum, Lachrymal, Uterine
Picks	Retinal, Membrane

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A-67/5, G. T. KARNAL ROAD, INDUSTRIAL AREA, DELHI – 110 033, INDIA

List of the Medical Devices covered by the EC Certificate:

Product Group 3 - Surgical Instruments (Non-sterile)	
Product	Type of Models
Chisel, Gouge & Mallet	Bone, Lachrymal
Forceps	IRIS, Dressing, Micro, Needle, Fixation, Colibri, Corneal, Tying, Suture, Utility, Toothed, Serrated, Plain, Capsulorhexis, Superior Rectus, Tissue, Angled, Cilia, Epilation, Corneal Graft, Chalazion, Entropium, Advancement, Lens Holding, Lens Folding, IOL, Haemostatic, Fascia Stripper, Forceps for Meibum Gland, Lens Expresser, Eye Lid Compression, Rongeur, Uterine, Obstetrics, Vulsellum, Biopsy, Ovarian, Hysterectomy, Mosquito, Artery, Cheatle
Dry Eye Instruments	Dry Eyes Expressers, Dry Eyes Forceps of Different Kinds & Types
Eye Instrument Sets	Cataract Extraction Set, Chalazion Set, D. C. R. Set, Entropium Correction Set, Enucleation Set, Evisceration Set, Fascia Lata Set, Foreign Body Removal Set, Glaucoma Set, Keratoplasty Set, Lid Surgery Set, Mini Cataract Set, Mini D.C.R. Set, Mini Glaucoma Set, Mini Lid Surgery Set, Nasal Lachrymal Set, Orbital Set, Phacoemulsification Set, Probing Set, Pterygium Set, Ptosis Set, Squint Surgery Set, Strabismus Set, Vitreoretinal Set, Eye Bank Set, SICS Instrument Set, Cataract/ Phaco Set, Titanium (Set of 10 Instruments), Cataract/ Phaco Set, Titanium (Set of 7 Instruments), Cataract/ Phaco Set, Titanium (Set of 4 Instruments), Cataract/ Phaco Set, Titanium (Set of 6 Instruments)
Vitreoretinal Instruments Forceps	Capsulorhexis, End Gripping, Membrane Peeling, Foreign Body, Plain, Serrated, Fixed Tips, Changeable Tips, 23 G & 20 G
Vitreoretinal Instruments Scissors	Straight, Curved, Angled, Fixed Tips, Changeable Tips, 23 G & 20 G
Trephines, Blocks & Stands	Corneal, Chalazion, Fixed
Punch	Rongeur, Membrane, Corneo Scleral, Bone, Skin, Biopsy
Rings	Fixation, Scleral, Flieringa



Authorized Signature

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Annexure to Certificate

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List of the Medical Devices covered by the EC Certificate:

Product Group 3 – Surgical Instruments (Non-sterile)	
Product	Type of Models
Scissors	Eye, Vitreoretinal, IRIS, Stitch Cutting, Enucleation, Corneal, Tenotomy, Synechia, Mayo, Metzenbaum, Micro, Laryngeal, Episiotomy, Umbilical, Gynecological, Castroviejo, Strabismus, Knapp, Steven, Westcott, Noyes, Vannas, Barraquer, Dewecker, Katzin, Troutman, Dissecting, IOL/ Lens Cutting, Straight, Curved, Angled, Tonsil
Needle Holder	Standard, Corneal, Straight, Curved, Angled, Micro, With Catch, Without Catch, Mayo, Castroviejo, Barraquer, Kalt, Arruga, Troutman, Lims, Pierce, McPherson, Steven, Keswani, Gillies
Reusable Cannulas	Air Injection, Retro Bulbar, Cyclodialysis, A. C. Wash (Anterior Chamber), Irrigating, Lachrymal, Spatulated, Plain, Serrated, Straight, Angled, Curved, Aspirating, Viscoelastic, Cortex Extractor, Irrigating and Aspirating J Shaped, J Shaped Irrigating and Aspirating, Capsule Polisher, Hydro-Dissection, Hydrodelineation, Irrigating Vectis, Irrigating Lens Manipulating, Infusion, A.C. Maintainer, Anterior Chamber Maintainer, Suction, Irrigating Handles, Back Flush Hand Pieces, Irrigating Choppers, Irrigating Hand Piece, Aspirating Hand Piece, Uni-Polar, Bipolar
Product Group 4 – Ophthalmic Equipments (Non-Sterile)	
Keratometer	—
Lensometer	—
Trial Lens Sets & Frames (Refraction Sets)	Trial Lens Set Reduced Aperture, Trial Lens Set Full Aperture, Trial Frames for Reduced For Reduced Aperture, Trial Frames for Full Aperture, Illuminated & Non- Illuminated
Operating Lights	Head Light Halogen, Cold Light Source, O. T. Lights
Product Group 5 – Eye OPD & O. T. Furniture	
Surgeon Chair	—
O. T. Table	—
Refraction Unit	Manual & Motorised



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List of the Medical Devices covered by the EC Certificate:

Product Group 6 – Miscellaneous Ophthalmic Products	
Product	Types of Models
Retinoscopy Rack	—
Prism Bar	Horizontal, Vertical & Loose
Retinoscope Mirror	Single & Double
Drum	DV, Rotating, Roller, Motorized & Near Vision
Instrument Table	Manual



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