

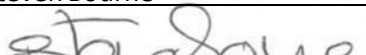
Declaration of Conformity

for Single Use Ophthalmic instruments.

European Communities Council Directive 93/42/EEC as amended by 2007/47/EC concerning Medical Devices as transposed into European national law by the member states

The undersigned declares that the products described in this document meet the Council Directive provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Single use ophthalmic instruments
Legal Manufacturer: (Name on Label)	Sihong Surgitrac Co limited 2 Xihu Road, Sihong Industrial Park Jiangsu 223900 China.
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Use:	Used in ophthalmic surgery
MD Directive Classification:	Class IIa under rule 6
Notified Body and CE:	TUV Rheinland 0197 (Shanghai) CE DD60147761 0001 Expires 06/05/2024
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2 nd Flr., Tower Street, Swatar, BKR 4013 Malta.
Medical Device Directive Assessment Route:	Medical Devices Directive 93/42/EEC Annex V & articles 12 and 14, this Declaration of Conformity and the registration of persons responsible for placing the devices on the market.

Name Steven Bourne **Position** MD Surgitrac Group
Signed  **Date** 04/08/2021

This Declaration of Conformity will remain valid until 26 of May 2024.

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Appendix I – Applicable Standards

This present declaration is also in conformity with the following European standards and Common Specifications:

Standard/Document Name	Description
93/42/EEC	Council Directive concerning medical devices as amended by Directive 2007/47/EC
EN 1041:2008	Information supplied by the manufacturer of medical devices
EN ISO 13485:2016	Medical Devices – Quality Management Systems – Requirements for Regulatory Purposes
EN ISO 14971:2012	Medical Devices – Application of Risk Management to Medical Devices
EN ISO 15223-1:2016	Medical devices – Symbols to be used with medical device labels, labelling and information to be supplied

Appendix II – Product Listing/Schedule

Part/Catalogue Number	Description/Name	GMDN Code
CR01N	Curette small	64301
CR02N	Curette medium	64301
CR03N	Curette large	64301
CR05N	Curette double ended M&L	64301
CS01N	Chalazion clamp small	62673
CS02N	Chalazion clamp large	62673
CS03N	Chalazion clamp medium	62673
PD01N	Punctal dilator sharp	44359
PD02N	Punctal dilator blunt	44359
PD03N	Punctal dilator double ended	44359
PD04N	Punctal dilator	44359
PD05N	Bowmans probe 00-0	44359
PD06N	Bowmans probe 00-000	44359
PD07N	Punctal dilator and lacrimal probe double ended.	44359
PD08N	Lacrimal probe	44359
SA11N	Westcott conjunctival scissors	63487
SA12N	Moorfields forceps	62489
SA13N	Stallard scissors	63486
SA14N	Westcott dolphin nosed scissors	63487
SA15N	Westcott dolphin nosed scissors blunt tipped	63487
SA17N	Moorfields fine forceps	62489

SC01N	Broad gauge wire speculum	46959
SC03N	Bangerter adult speculum	46959
SC04N	Bangerter paediatric speculum	46959
SC05N	Kratz solid bladed speculum	46959
SC07N	Wide angled closed loop speculum	46959
SC08N	Solid blade adjustable speculum	46959
SC09N	Kratz Barraquer wire closed loop speculum	46959
SC10N	Kratz paediatric 10mm closed loop speculum	46959
SC11N	Kratz Barraquer open loop wire speculum	46959
SC12N	Temporal speculum	46959
SC13N	Kratz speculum open loop	46959
SC14N	Paediatric 6mm bladed speculum	46959
SC15N	Neonate 4mm bladed speculum	46959
SC16N	Pierce adjustable speculum	46959
SC17N	Solid bladed speculum.	46959
SC19N	Straight tying forceps 85mm	62489
SC20N	Colibri toothed forceps 85mm	62489
SC21N	Straight toothed forceps fine	62489
SC22N	Colibri toothed forceps 11cm	62489
SC23N	Scleral depressor bulbous end	64317
SC24N	Scleral depressor hammer shape	64317
SC25N	Scleral depressor double ended	64317
SC29N	Capsulorhexis forceps -2.4 curved tipped	62489
SC29MN	MICS Capsulorhexis forceps curved tipped	62489
SC30N	Capsulorhexis forceps short handled	62489
SC31N	Capsulorhexis forceps straight tipped	62489
SC32N	Capsulorhexis forceps curved tipped	62489
SC33N	Capsulorhexis forceps x action	62489
SC33MN	MICS capsulorhexis forceps x action	62489
SC34N	Capsulorhexis forceps round bodied	62489
SC34MN	MICS Capsulorhexis forceps round bodied curved tipped	62489
SC35N	Swan neck forceps	62489
SC36N	Utrata non-toothed capsulorhexis forceps	62489
SC38N	Bonn forceps short handled 85mm	62489
SC39N	Chopper and dialler double ended	59037
SC41N	Y nucleus rotator	59037
SC42N	Claw phaco chopper	59037
SC43N	Phaco chopper	59037
SC44N	Koch chopper	59037
SC45N	Greens chopper	59037
SC46N	Lens dialler	59037
SC47N	Drysdale nucleus spatula	59037
SC48N	Mushroom nucleus manipulator	59037
SC49N	Straight notched forceps	62489
SC50N	Curved notched forceps	62489
SC51N	Lens folding forceps	62489
SC52N	Intraocular lens implantation forceps	62489

SC53N	Lens introducing forceps	62489
SC54N	St Martins forceps 1 in 2 teeth.	62489
SC55N	Hoskins forceps 85mm	62489
SC56N	Bishops forceps	62489
SC58N	Epilation-cilia forceps	62489
SC59N	Adsons forceps 12.5cm	62489
SC60N	Jewellers forceps	62489
SC61N	Suture needle holder curved	47568
SC62N	Needle holder blunt with lock.	47568
SC63N	Iris repositor	59037
SC65N	Mendez gauge	12442
SC71N	St Tying forceps	62489
SC72N	McPherson forceps	62489
SC73N	McPherson tying forceps short handled 83mm	62489
SC74N	Girard straight tying forceps	62489
SC80N	Ong scissors	63487
SC81N	Vannas fine scissors	63487
SC82N	Castroviejo corneal scissors (right)	63487
SC83N	Castroviejo corneal scissors (left)	63487
SC85N	Capsule polisher	59037
SC90N	Jones chopper	59037
SC91N	Chavasse hook	59037
SC95N	Chopper and Kuglen horizontal double ended	59037
SC96N	Iris scissors straight and pointed	63487
SC97N	Dennis cleaver	59037
SC99N	Lindgren forceps	62480
SC100N	Govan manipulator	59037
SC101N	Pisacano Neuham manipulator	59037
SC102N	Govan manipulator phaco chopper double ended	59037
SC103N	Neonate paediatric speculum	46959
SC104N	Denis sclerectomy forceps	62489
SC105N	Troutman curved tying forceps	62489
SC106N	Le Buisson manipulator	59037
SC107N	Kratz Barraquer open loop wire speculum (blue)	46959
SC108N	Vannas scissors curved	63487
SC109N	Osher scissors	63487
SC110N	Castroviejo scissors curved and blunt	63487
SC111N	Castroviejo scissors straight	63487
SC112N	Intra-ocular lens removal forceps	62489
SC113N	Adsons forceps fine and serrated.	62489
SC114N	Needle holder curved	47568
SC115N	Fine clawed forceps 2 into 1	62489
SC116N	Iris forceps	62489
SC117N	Jayles forceps	62489
SC118N	Castroviejo needle holder with lock	47568
SC119N	Adsons forceps non-toothed	62489
SC120N	Curved suture removal forceps	62489

SC121N	Lieberman speculum stainless steel	46959
SC124N	Heavy gauge wire speculum	46959
SC126N	Clarke speculum	46959
SC127N	Epilation forceps	62489
SC128N	Iris pointed forceps	62489
SC129N	Bonn forceps 10.5cm	62489
SC130N	Corneal marker capsulorhexis guide	12442
SC132N	Kratz Barraquer closed loop wire speculum	46959
SC133MN	MICS Capsulorhexis forceps straight tipped	62489
SC134MN	MICS Capsulorhexis forceps round bodied straight tipped	62489
SC135N	Bangerter speculum	46959
SC142N	Barraquer Needle holder	47568
SC143N	Koch phaco spatula	59037
SC144N	Sinsky hook govan manipulator double ended	59037
SC146N	Lester hook	59037
SC147N	Phaco chopper mushroom manipulator double ended	59037
SC148N	Nagahara cleaver	59037
SC150N	Wire speculum open loop	46959
SCL05N	Barraquer solid blade speculum long	46959
SCM01	Capsulorhexis forceps MICS -2.2	62489
SG01N	General scissors sharp pointed	63487
SG02N	Mosquitos forceps 12.5cm	62489
SG03N	Trabeculectomy punch	62437
SG04N	Braunstein fixed calliper 1.8mm thick x 68mm long	57833
SG04BN	Braunstein fixed calliper 0.8mm thick x 68mm long	57833
SG04CN	Braunstein fixed calliper 1.9mm thick x 70mm long	57833
SG04EN	Braunstein fixed calliper 1.8mm thick x 70mm long	57833
SG05N	Castroviejo adjustable calliper	35787
SG06N	General scissors blunt end	63487
SG07N	Strabismus scissors	63487
SG08N	Jaffe lid retractor 14mm blades	46959
SG09N	Jaffe lid retractor 9mm blades	46959
SG10N	Jameson strabismus hook 5mm	59037
SG11N	Jameson strabismus hook 8mm	59037
SG12N	Thornton fixation ring 13mm	64287
SG13N	Thornton fixation ring 16mm	64287
SG14N	General scissors long blunt end	63487
SG15N	Kuglen hook	59037
SG17N	Eye lid plate	64302
SG18N	Muscle hook with hole	59037
SG19N	Scleral marker double ended	35787
SG20N	Desmarres retractor 18mm wide	59037
SG22N	Mosquito forceps curved	62489
SG23N	Stevens scissors curved	63487
SG26N	Heleveston muscle hook small	59037
SG27N	Heleveston muscle hook large	59037
SG28N	Gilles hook small	59037

SG30N	Metzenbaum curved pointed scissors	63487
SG31N	Stevens tenotomy scissors pointed	63487
SG32N	Ball tip muscle hook	59037
SG33N	Halstead mosquito straight forceps	62489
SG34N	Enucleation scissors	63487
SG35N	Dressing scissors curved round ends	63487
SG37N	Guthrie hook	59037
SG38N	Kelly forceps	62489
SG92N	Bull dog clip-small	62480
SG93N	Heleveston ruler	57833
SR01N	Lenticule extraction forceps	62489
SR02N	Lasik femto separator and elevator double ended	59037
SR03N	Sinskey and reverse sinskey hook	59037
SR04N	Corneal ring pusher	59037
SR05N	Corneal ring pocketing hook	59037
SR06N	Corneal ring pocket spreader	59037
SR07N	Corneal ring forceps Keraring	62489
SR08N	Corneal ring forceps INTACS	62489
SR10N	Bladed adjustable speculum	46959
SR11N	Kratz screw adjustable open loop speculum	46959
SR12N	Neoris pocketing spatula double ended	59037
SR14N	Lasik flap lifting forceps	62489
SR21N	Lasik corneal marker	12442
SR31N	Lasik flap elevator	59037
SR32N	Universal flap lifter	59037
SR34N	Intra-lasik flap separator	59037
SR40N	CK Lasik marker (target centre)	12442
SR41N	Alcohol well 9mm	64316
SR42N	Alcohol well 8mm	64316
SR43N	Alcohol well 7mm	64316
SR51N	Epi peeler	59037
SR60N	Epi peeler D shaped	59037
SR61N	Epi peeler rectangle shape	59037
SR70N	Reinstein Lenticule separator	59037
SR71N	Lasik flap forceps	62489
SR72N	Corneal marker 8 lines	12442
SR91N	Implantation Forceps	62489
SR100N	Corneal epithelium spatula round	59037
SR101N	S Marker	62489
SR102N	Kocaba DMEK forceps	62489
SR103N	Lasik flap separator and elevator straight double ended	59037
SR104N	Reinstein Lenticule separator elevator double ended	59037
SR105N	17mm Trephine	46251
SR106N	18mm Trephine	46251
SR107N	19mm Trephine	46251
SR108N	Paton spatula and spoon double ended	59037
SR109N	Bernheim hook DSAEK.	59037
SR110N	16MM Trephine	46251

Version History

Version	Compiled by	Date	Description
3.0	RP Johns	10/03/2021	Removed self-certified from document. Date of expiry added. Rule 6 added.
3.1	R P Johns	29/03/2021	Corrected SC46 description and removed duplication on SC47.
3.2	R P Johns	03/08/2021	Updated CE expiration date and certificate Number.
3.3	R P Johns	04/08/2021	Updated expiry date.
3.4	R P Johns	01/09/2021	SR72 and SR91 corrections to description and GMDN code.
3.5	R P Johns	08/09/2021	N added to codes to denote sold as non-sterile bulk packed for packing manufacturers.