

## 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.

<b>General Product Name:</b>	Single use ophthalmic instruments
<b>Legal Manufacturer: (Name on Label)</b>	Sihong Surgitrac Co limited 2 Xihu Road, Sihong Industrial Park Jiangsu 223900 China.
<b>Variants:</b>	As per Appendix II (This document) – Product Listing/Schedule
<b>Intended Use:</b>	Used in ophthalmic surgery
<b>MD Directive Classification:</b>	Class IIa under rule 6
<b>Notified Body and CE:</b>	TUV Rheinland 0197 (Shanghai) CE DD60123069 0001 Expires 17/07/2022
<b>EU Authorised Representative:</b>	Advena Limited. Tower Business Centre, 2 <sup>nd</sup> Flr., Tower Street, Swatar, BKR 4013 Malta.
<b>Medical Device Directive Assessment Route:</b>	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** 10/03/2021

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
<b>CR01</b>	<b>Curette small</b>	<b>64301</b>
CR02	Curette medium	<b>64301</b>
CR03	Curette large	<b>64301</b>
CR05	Curette double ended M&L	<b>64301</b>
CS01	Chalazion clamp small	62673
CS02	Chalazion clamp large	62673
CS03	Chalazion clamp medium	62673
<b>PD01</b>	<b>Punctal dilator sharp</b>	<b>44359</b>
PD02	Punctal dilator blunt	<b>44359</b>
PD03	Punctal dilator double ended	<b>44359</b>
PD04	Punctal dilator	<b>44359</b>
PD05	Bowmans probe 00-0	<b>44359</b>
PD06	Bowmans probe 00-000	<b>44359</b>
PD07	Punctal dilator and lacrimal probe double ended.	<b>44359</b>
PD08	Lacrimal probe	<b>44359</b>
SA11	Westcott conjunctival scissors	63487
SA12	Moorfields forceps	62489
SA13	Stallard scissors	63486
SA14	Westcott dolphin nosed scissors	63487
SA15	Westcott dolphin nosed scissors blunt tipped	63487
<b>SA17</b>	<b>Moorfields fine forceps</b>	<b>62489</b>

SC01	Broad gauge wire speculum	46959
SC03	Bangerter adult speculum	46959
SC04	Bangerter paediatric speculum	46959
SC05	Kratz solid bladed speculum	46959
SC07	Wide angled closed loop speculum	46959
SC08	Solid blade adjustable speculum	46959
SC09	<b>Kratz Barraquer wire closed loop speculum</b>	46959
<b>SC10</b>	Kratz paediatric 10mm closed loop speculum	46959
SC11	Kratz Barraquer open loop wire speculum	46959
SC12	Temporal speculum	46959
SC13	Kratz speculum open loop	46959
SC14	Paediatric 6mm bladed speculum	46959
SC15	Neonate 4mm bladed speculum	46959
SC16	<b>Pierce adjustable speculum</b>	46959
<b>SC17</b>	Solid bladed speculum.	46959
SC19	Straight tying forceps 85mm	62489
SC20	Colibri toothed forceps 85mm	62489
SC21	Straight toothed forceps fine	62489
SC22	Colibri toothed forceps 11cm	62489
SC23	Scleral depressor bulbous end	64317
SC24	Scleral depressor hammer shape	64317
SC25	Scleral depressor double ended	64317
SC29	Capsulorhexis forceps -2.4 curved tipped	62489
SC29M	MICS Capsulorhexis forceps curved tipped	62489
SC30	Capsulorhexis forceps short handled	62489
SC31	Capsulorhexis forceps straight tipped	62489
<b>SC32</b>	<b>Capsulorhexis forceps curved tipped</b>	62489
SC33	Capsulorhexis forceps x action	62489
SC33M	MICS capsulorhexis forceps x action	62489
SC34	Capsulorhexis forceps round bodied	62489
SC34M	MICS Capsulorhexis forceps round bodied curved tipped	62489
SC35	Swan neck forceps	62489
SC36	Utrata non-toothed capsulorhexis forceps	62489
SC38	Bonn forceps short handled 85mm	62489
SC39	Chopper and dialler double ended	59037
SC41	Y nucleus rotator	59037
SC42	Claw phaco chopper	59037
<b>SC43</b>	<b>Phaco chopper</b>	59037
SC44	Koch chopper	59037
SC45	Greens chopper	59037
SC47	Lens dialler	59037
SC48	Drysdale nucleus spatula	59037
SC48	Mushroom nucleus manipulator	59037
SC49	Straight notched forceps	62489
<b>SC50</b>	<b>Curved notched forceps</b>	62489
SC51	Lens folding forceps	62489
SC52	Intraocular lens implantation forceps	62489

SC53	Lens introducing forceps	62489
SC54	St Martins forceps 1 in 2 teeth.	62489
SC55	Hoskins forceps 85mm	62489
SC56	Bishops forceps	62489
SC58	Epilation-cilia forceps	62489
SC59	Adsons forceps 12.5cm	62489
SC60	Jewellers forceps	62489
SC61	Suture needle holder curved	47568
SC62	Needle holder blunt with lock.	47568
SC63	Iris repositor	59037
<b>SC65</b>	<b>Mendez gauge</b>	<b>12442</b>
SC71	St Tying forceps	62489
SC72	McPherson forceps	62489
SC73	McPherson tying forceps short handled 83mm	62489
SC74	Girard straight tying forceps	62489
SC80	Ong scissors	63487
SC81	Vannas fine scissors	63487
SC82	Castroviejo corneal scissors (right)	63487
SC83	Castroviejo corneal scissors (left)	63487
SC85	Capsule polisher	59037
SC90	Jones chopper	59037
<b>SC91</b>	<b>Chavasse hook</b>	<b>59037</b>
SC95	Chopper and Kuglen horizontal double ended	59037
SC96	Iris scissors straight and pointed	63487
SC97	Dennis cleaver	59037
SC99	Lindgren forceps	62480
SC100	Govan manipulator	59037
SC101	Pisacano Neuham manipulator	59037
<b>SC102</b>	<b>Govan manipulator phaco chopper double ended</b>	<b>59037</b>
SC103	Neonate paediatric speculum	46959
SC104	Denis sclerectomy forceps	62489
SC105	Troutman curved tying forceps	62489
SC106	Le Buisson manipulator	59037
SC107	Kratz Barraquer open loop wire speculum (blue)	46959
SC108	Vannas scissors curved	63487
SC109	Osher scissors	63487
SC110	Castroviejo scissors curved and blunt	63487
SC111	Castroviejo scissors straight	63487
SC112	Intra-ocular lens removal forceps	62489
SC113	Adsons forceps fine and serrated.	62489
SC114	Needle holder curved	47568
<b>SC115</b>	<b>Fine clawed forceps 2 into 1</b>	<b>62489</b>
SC116	Iris forceps	62489
SC117	Jayles forceps	62489
SC118	Castroviejo needle holder with lock	47568
SC119	Adsons forceps non-toothed	62489
SC120	Curved suture removal forceps	62489

SC121	Lieberman speculum stainless steel	46959
SC124	Heavy gauge wire speculum	46959
SC126	Clarke speculum	46959
SC127	Epilation forceps	62489
SC128	Iris pointed forceps	62489
<b>SC129</b>	<b>Bonn forceps 10.5cm</b>	<b>62489</b>
<b>SC130</b>	<b>Corneal marker capsulorhexis guide</b>	<b>12442</b>
SC132	Kratz Barraquer closed loop wire speculum	46959
SC133M	MICS Capsulorhexis forceps straight tipped	62489
SC134M	MICS Capsulorhexis forceps round bodied straight tipped	62489
SC135	Bangerter speculum	46959
SC142	Barraquer Needle holder	47568
SC143	<b>Koch phaco spatula</b>	<b>59037</b>
<b>SC144</b>	<b>Sinsky hook govan manipulator double ended</b>	<b>59037</b>
SC146	Lester hook	59037
SC147	Phaco chopper mushroom manipulator double ended	59037
SC148	Nagahara cleaver	59037
SC150	Wire speculum open loop	46959
SCL05	Barraquer solid blade speculum long	46959
SCM01	Capsulorhexis forceps MICS -2.2	62489
SG01	General scissors sharp pointed	63487
SG02	Mosquitos forceps 12.5cm	62489
SG03	Trabeculectomy punch	62437
SG04	Braunstein fixed calliper 1.8mm thick x 68mm long	57833
SG04B	Braunstein fixed calliper 0.8mm thick x 68mm long	57833
<b>SG04C</b>	<b>Braunstein fixed calliper 1.9mm thick x 70mm long</b>	<b>57833</b>
SG04E	Braunstein fixed calliper 1.8mm thick x 70mm long	57833
SG05	Castroviejo adjustable calliper	35787
SG06	General scissors blunt end	63487
SG07	Strabismus scissors	63487
SG08	Jaffe lid retractor 14mm blades	46959
SG09	Jaffe lid retractor 9mm blades	46959
SG10	Jameson strabismus hook 5mm	59037
SG11	Jameson strabismus hook 8mm	59037
SG12	Thornton fixation ring 13mm	64287
SG13	Thornton fixation ring 16mm	64287
SG14	General scissors long blunt end	63487
SG15	Kuglen hook	59037
SG17	Eye lid plate	64302
SG18	Muscle hook with hole	59037
SG19	Scleral marker double ended	35787
SG20	Desmarres retractor 18mm wide	59037
SG22	Mosquito forceps curved	62489
SG23	Stevens scissors curved	63487
SG26	Heleveston muscle hook small	59037
SG27	Heleveston muscle hook large	59037
SG28	Gilles hook small	59037

SG30	Metzenbaum curved pointed scissors	63487
SG31	Stevens tenotomy scissors pointed	63487
SG32	Ball tip muscle hook	59037
SG33	Halstead mosquito straight forceps	62489
SG34	Enucleation scissors	63487
SG35	Dressing scissors curved round ends	63487
SG37	Guthrie hook	59037
SG38	Kelly forceps	62489
SG92	Bull dog clip-small	62480
SG93	Heleveston ruler	57833
SR01	Lenticule extraction forceps	62489
SR02	Lasik femto separator and elevator double ended	59037
SR03	Sinsky and reverse sinkey hook	59037
SR04	Corneal ring pusher	59037
SR05	Corneal ring pocketing hook	59037
SR06	Corneal ring pocket spreader	59037
SR07	Corneal ring forceps Keraring	62489
SR08	Corneal ring forceps INTACS	62489
SR10	Bladed adjustable speculum	46959
SR11	Kratz screw adjustable open loop speculum	46959
SR12	Neoris pocketing spatula double ended	59037
SR14	Lasik flap lifting forceps	62489
SR21	Lasik corneal marker	12442
SR31	Lasik flap elevator	59037
SR32	Universal flap lifter	59037
SR34	Intra-lasik flap separator	59037
SR40	Ck Lasik marker (target centre)	12442
SR41	Alcohol well 9mm	64316
SR42	Alcohol well 8mm	64316
SR43	Alcohol well 7mm	64316
SR51	Epi peeler	59037
SR60	Epi peeler D shaped	59037
SR61	Epi peeler rectangle shape	59037
SR70	Reinstein Lenticule separator	59037
SR71	Lasik flap forceps	62489
SR91	Corneal marker 8 lines	12442
SR100	Corneal epithelium spatula round	59037
SR101	S Marker	62489
SR102	Kocaba DMEK forceps	62489
SR103	Lasik flap separator and elevator straight double ended	59037
SR104	Reinstein Lenticule separator elevator double ended	59037
SR105	17mm Trephine	46251
SR106	18mm Trephine	46251
SR107	19mm Trephine	46251
SR108	Paton spatula and spoon double ended	59037
SR109	Bernheim hook DSAEK.	59037
SR110	16MM Trephine	46251

## Version History

Version	Compiled by	Date	Description
3.0	R P Johns	10/03/2021	Removed self-certified from document. Date of expiry added. Rule 6 added.
3.0.1	R P Johns	13/10/2021	Medical device directive assessment route