

CERTIFICATE

No. 72013



This is to certify the Quality Management System for Medical Devices of the company



Cilita LLC

office 702, bld. 20, Moskovskoye Shosse
390044 Ryazan
Russia

Building 45, 7, Stankozavodskaya street, Ryazan, 390042, Russia

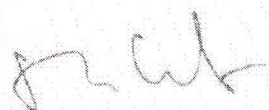
has been assessed and found to be in compliance with the Standard

ISO 13485:2016

applicable to

Manufacturing, quality control, packaging, storage and distribution of non-active(non-implantable) medical devices: microsurgical and surgical instruments, including ophthalmic instruments.

The certificate has been issued under No. 72013 for the registration period from 11 December 2020 to 27 November 2023.
The first certificate date of issue is 28 November 2017.


Approved by


Printed by



validity code FD5A8888-A51

Check the validity of this certificate using this code at www.ll-c.info

LL-C (Certification) Czech Republic a.s. | Pobřežní 620/3, 186 00 Praha 8

www.ll-c.net





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CERTIFICATE OF CONFORMANCE

We, **CILITA Ltd.**, Of. 702, 20 Moskovskoye shosse, Ryazan 390044, Russia, hereby declare that:

The following products listed hereunder have been registered with the European Competent Authority in Germany (Regierungspräsidium Darmstadt, Abteilung Arbeitsschutz und Umwelt, Dezernat IV/F 45.2, Address: Gutleutstraße 114, Frankfurt am Main 60327 Hessen, Code: DE/CA24), date of registration: 29-03-2019

Name of device: **Ophthalmic Reusable Surgical Instruments**

Category code: 08

Category: Ophthalmic and Optical Products

Class: I

Notification type: Initial notification

Group	UMDNS code	English short description	German short description	Registration number	Medical Devices Form Number
Blade Holders, Calipers & Markers	12-235	Knife Handles	Messergriff	DE/CA24/159733/024	00275130
	16-415	Calipers, Ophthalmic	Tasterzirkel, ophthalmologisch	DE/CA24/159733/023	00275136
	12-442	Markers, Ocular	Marker, okular	DE/CA24/159733/022	00275141
Diamond & Sapphire Knives	12-241	Knives, Cataract	Messer, Katarakt	DE/CA24/159733/021	00275142
	12-247	Knives, Keratome	Messer, Keratom	DE/CA24/159733/020	00275143
Forceps	16-209	Forceps, Ophthalmic	Zange, ophthalmologisch	DE/CA24/159733/019	00275148
	16-450	Clamps, Ophthalmic	Klemme, ophthalmologisch	DE/CA24/159733/018	00275149
Hooks	12-036	Hooks, Strabismus	Haken, Strabismus	DE/CA24/159733/031	00275201
	12-034	Hooks, Scleral Fixation	Haken, sklerale Fixation	DE/CA24/159733/030	00275202
Miscellaneous	11-084	Curets	Kürette	DE/CA24/159733/047	00275239
	17-544	Inserters, Intraocular Lens	Einsetzgerät, Intraokularlinsen	DE/CA24/159733/046	00275241
	12-319	Lens Loops	Starschlinge	DE/CA24/159733/045	00275242
	11-259	Dilators, Lacrimal	Dilatator, lakrimal	DE/CA24/159733/044	00275243
	16-025	Spuds, Eye	Fremdkörpernadel	DE/CA24/159733/043	00275244
	16-465	Depressors, Orbital	Depressor, Augenhöhle	DE/CA24/159733/042	00275246
	13-232	Punches, Corneoscleral	Stanze, Korneoskleral	DE/CA24/159733/041	00275247
Needle Holders	12-726	Needle Holders	Nadelhalter	DE/CA24/159733/050	00275248
Phaco-emulsification	15-225	Hooks, Other	Haken, sonstige	DE/CA24/159733/049	00275250



Probes	13-119	Probes, Eye	Sonde, Auge	DE/CA24/159733/048	00275251
	13-120	Probes, Eye, Lacrimal	Sonde, Auge, lakrimal	DE/CA24/159733/040	00275252
Retractors	13-381	Retractors, Eye	Wundhaken, Auge	DE/CA24/159733/039	00275253
	13-385	Retractors, Orbital	Wundhaken, Orbita	DE/CA24/159733/038	00275254
Scissors	13-485	Scissors, Eye	Schere, Auge	DE/CA24/159733/037	00275256
	13-487	Scissors, Eye, Enucleation	Schere, Auge, Enukleation	DE/CA24/159733/036	00275257
	13-488	Scissors, Eye, Iris	Schere, Auge, Iris	DE/CA24/159733/035	00275258
	13-486	Scissors, Eye, Cornea	Schere, Auge, Kornea	DE/CA24/159733/034	00275262
	15-246	Scissors, Eye, Other	Schere, Auge, sonstige	DE/CA24/159733/033	00275264
	13-490	Scissors, Eye, Tenotomy	Schere, Auge, Tenotomie	DE/CA24/159733/060	00275265
	13-489	Scissors, Eye, Suture	Schere, Auge, Wundnaht	DE/CA24/159733/059	00275266
Spatulas	13-648	Spatulas, Eye	Spatel, Auge	DE/CA24/159733/058	00275267
Speculums	13-663	Specula, Eye	Spekulum, Auge	DE/CA24/159733/057	00275268
Sterilizing Trays	12-143	Trays, Instrument	Tablett, Instrument	DE/CA24/159733/053	00275270
Vitreoretinal	16-209	Forceps, Ophthalmic	Zange, ophthalmologisch	DE/CA24/159733/054	00275271
	13-485	Scissors, Eye	Schere, Auge	DE/CA24/159733/052	00275272

Authorized Representative - Reporting organization pursuant to § 25 Medical Devices Act, MPG:

Arazy Group GmbH, Address: AM KALKOFEN 8, WÖLLSTADT 61206, Hessen, Germany, Phone +49 (0)6034 90 59 49-0, E-mail: germany@arazygroup.com, Code: DE/0000048219

Safety officer for medical devices pursuant to § 30 (2) Medical Devices Act, MPG:

Miki Melach, Address: AM KALKOFEN 8, WÖLLSTADT 61206, Hessen, Germany, Phone +49 (0)6034 90 59 49-0, E-mail: germany@arazygroup.com

Manufacturer:

Cilita Ltd., Of. 702, 20, Moskovskoye shosse, Ryazan 390044 Russia, Phone +74912779678, E-mail: sales@cilita.com

By submitting information to Regierungspräsidium Darmstadt, the legal requirements for registration have been met. Cilita Ltd. complies with the requirements of the Medical Device Directive 93/42 EEC and the above products can be CE marked according to the above directive.

On behalf of Cilita Ltd.

Lyudmila Moskvina
Director, Cilita Ltd.

Date: 02.10.2019

