



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, Korneoscleral	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, Enukeation	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:

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

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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

