



Excellent Instruments for Professional Hands

Form: TF.002

Rev.: 3.0

Rev. Date: 28/01/19

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## Declaration of Conformity

Manufacturer: Cilita Ltd.

office 702, 20 Moskovskoye shosse

Ryazan, Russia, 390044



Products: Ophthalmic Reusable Surgical Instruments,

Placed the products in the European market, declare that our products conform and meet the essential requirements set out in Annex I of the Medical Device Directive 93/42 EEC.

Product:

Model:

Class

Ophthalmic Reusable Surgical Instruments

I

- Retractors
- Sapphire Knives
- Scissors
- Spatulas
- Speculums
- Sterilizing Trays
- Vitreoretinal

- Blade Holders, Calipers & Markers
- Diamond Knives
- Forceps
- Hooks
- Miscellaneous
- Needle Holders
- Phacoemulsification
- Probes

Within those requirements we prepared the required technical documentation, put into place corrective action and vigilance procedures and have appointed Arazy Group GmbH, The Squire 12, Am Flughafen, 60549 Frankfurt am Main, Deutschland/ Germany, Tel: +49-60-34-9059-49-0, to act as our Authorized Representative in the European Community.

Full Name: Ludmila Moskvina

Position: Director

Date: 28/01/2019

Signature: \_\_\_\_\_





# CERTIFICATE

No. 70565



This is to certify that the Quality Management System of Medical Devices of



**Cilita LLC**

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

**including workshop:**

Stankozavodskaya Str., 7 bld. 45, 390042 Ryazan, 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. **70565** for the registration period from 18<sup>th</sup> December 2018 to 27<sup>th</sup> November 2020. The first certificate date of issue is 28<sup>th</sup> November 2017.



Approved by



Printed by



validity code: **9D9C66B2-B07**

Check the validity of this certificate using this code at [www.ll-c.net](http://www.ll-c.net)