

№ 185510

# CERTIFICATE

of conformity  
No. 72013



In compliance with requirements for technical documentation specified in Council Directive 93/42/EEC, this certificate applies to the following products:

## OPHTHALMIC CILITA INSTRUMENTS

Technical Parameters: **Bladeholder, Ophthalmic Caliper, Corneoscleral Punch (Pliers), Ophthalmic Curette, Ophthalmic Depressor, Eye Probe, Forceps for anterior and posterior chamber, Forceps, Clamps, Ophthalmic Handle, Ophthalmic Hook, Injector, Irrigation / Aspiration Handle, Lens Manipulator, Ophthalmic Marker, Ophthalmic Needleholder, Ophthalmic Retractor, Scissors for anterior and posterior chamber, Ophthalmic Scissors, Ophthalmic Spatula, Screw Eye Speculum**

Technical file: **OPHTHALMIC CILITA INSTRUMENTS TF-01 dated 19.05.2021**

Assessment performed:

MDD class: **Class 1**

Applied standards: **EN ISO 15223-1, EN ISO 10993-1, EN ISO 14971**

produced by or for

«Cilita» LLC

Russia, Ryazan, 390044, Moscovskoye Shosse, 20, office 702

and produced in the manufacturing plant

Russia, Ryazan, 390044, Moscovskoye Shosse, 20. Office 702

This certificate confirms that all provisions described in relevant parts of the standard

**EN ISO 15223-1, EN ISO 10993-1, EN ISO 14971**

are addressed in the accompanying product documentation. The CE mark as shown below can be affixed, under the responsibility of the manufacturer, after the completion of EC declaration of conformity and compliance all the relevant directives.

This certificate was issued on **20 May 2021, is valid until 19 May 2024**, and is based on the evaluation of the technical file of the medical device. The voluntary certification does not imply an assessment of the production and it does not permit the use of a mark of conformity or of a safety mark of the LL-C (Certification). The holder of this certificate may use this certificate together with his EC declaration of conformity.

Prague, 20 May 2021

Ing. Lukáš Holub  
Deputy or Head of CB

