



ABOUT US

SIMERA

The Testing Laboratory Simera-TK LLC was established in December 2021 and operates in compliance with GOST ISO/IEC 17025 2019 «General Requirements for the Competence of Testing and Calibration Laboratories», accreditation criteria approved by Order of the Ministry of Economic Development of the Russian Federation No. 707 of 26 October 2020 and internal quality management system documents.

The Testing Laboratory Simera-TK LLC specializes in toxicity testing of medical devices in accordance with national and Eurasian Economic Union (EAEU) regulations.



SERVICES

The primary specialization of the Testing laboratory STK LLC is laboratory toxicity testing of a wide range of medical devices to confirm their safety for patient health.

Protocols of toxicological testing shall be annexed by the applicants to the package of documents for the medical device required for approval and market release in the Russian Federation and the Eurasian Economic Union (EAEU) or for the purpose of amending existing registration files.



PRODUCTS TESTED



internal and external prosthetic devices



surgical dressings



dental supplies



ophthalmic products



medical instruments



medical equipment



blood contacting medical devices



medical furniture




medical wear



EQUIPMENT



We use only certified test equipment and verified measuring instruments



- ✓ Analytical balance ВЛ 224В
- ✓ Spectrophotometer Unico 2804
- ✓ Hardware-software complex based on the Chromatec Crystal 5000 chromatograph, v.2
- ✓ Bench meter Ohaus AB33EC with electrode
- ✓ ELISA analyzer UNIPLAN АИФР 01
- ✓ Image analyzer AT 05 (for toxicity tests)
- ✓ Atomic absorption spectrometer A2
- ✓ Liquid chromatograph Shimadzu LC 20 prominence
- ✓ pH meter Mettler Toledo FiveEasy F20
- ✓ Laboratory centrifuge LMC 4200R
- ✓ Air incubator with electric control TS 1/80 СПУ



OUR BENEFITS



individual approach



highly trained personnel



strict compliance with Russian National Standards (GOST) requirements



our specialists will always answer all your questions and update you on current work status



strict compliance with laboratory testing deadlines



timely testing performance



sample calculations in accordance with GOST



timely preparation and issuance of test reports and all related documents



WE ARE TRUSTED



WE LOOK FORWARD TO A **SUCCESSFUL** PARTNERSHIP



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