

UKRAINE

CERTIFICATION BODY OF MANAGEMENT SYSTEMS

State Enterprise «Kharkivstandartmetrologiya»



80072
ISO/IEC 17021

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM

Registered in the Register
of the Certification Body
№UA8O072.19117325.4-2019
on November 4, 2019,
Valid until November 3, 2022

This certificate confirms that the quality management system is relatively
design, development, production, sterilization and sale of medical devices:

- Vaginal speculums single use;
- Single use gynecologic sets;
- Medical kits and operating sets;
- Manipulation and auxiliary products medical kits and their single use;
- Examination and surgical gloves sterile;
- Gynecological cervical brushes;
- Surgical dressing facilities and their kits;
- Incisive operating films TKderm® and operating antimicrobial and antibacterial films TKflex® sterile.

PSSC (Products and Services State Classifier) codes SC 016:2010 – 13.92.29-90.00; 14.19.23-93.00;
14.19.32-00.00; 14.19.43-00.00; 21.20.24-20.00; 22.19.60-00.00; 32.50.13,

which are carried out «FIRMA «TECHNOCOMPLEX» LIMITED LIABILITY COMPANY,
code USREOU (code United State Register of Enterprises and Organizations of Ukraine) 19117325,

Address head office: 03062, Kyiv, Peremogy ave., 65, Ukraine
production addresses:

20700, Cherkasy region, Smila, Peremogy st., 39
20704, Cherkasy region, Smila, Promyslova st., 22

according to the regulatory documents in force in Ukraine

meets the requirements **ДСТУ EN ISO 13485:2018 “Медичні вироби. Система управління якістю. Вимоги до регулювання” (EN ISO 13485:2016, IDT; ISO 13485:2016 «Medical devices – Quality management systems – Requirements for regulatory purposes», IDT)**

The compliance of the certified quality management system with the requirements of the specified standard is carried out by means of supervisory audits according to the Agreement on use of the certificate in the following terms:

the first - until 11/04/2020;

the second - until 11/04/2021,

which will be borne out by appropriate decisions to validate the certificate

The Certificate is issued by the **Management Systems Certification Body of State Enterprise "Kharkiv Regional Research and Production Center for Standardization, Metrology and Certification", 36 Myronosytska Str., Kharkiv, 61002, Ukraine (Accreditation Certificate No.80072)** based on the results of the audit and evaluation of the quality management system.

Deputy Head of Certification
and Conformity Assessment Body



V.V. Agarkov



The validity of the certificate can be checked by
State Enterprise «Kharkivstandartmetrologiya» tel. (057) 736-38-05