UKRAINE

CERTIFICATION BODY OF MANAGEMENT SYSTEMS
SE «KHARKOVSTANDARTMETROLOGY»

CERTIFICATE

OF QUALITY MANAGEMENT SYSTEM





Registered in the Register of the Certification Body under No. <u>UA8O072.31411528.4-2025</u> on March 19, 2025, Valid until February 28, 2027

This certificate hereby certifies that a quality management system in relation to

design and production:

air sterilizers and steam sterilizers, air thermostats,

vapor-formaldehyde chambers and medical furniture,

PSSC (Products and Services State Classifier) codes 32.50.12-00.00, 26.51.70-15.00, 32.50.30-50.99
name of products, PSSC codes SC 016:2010

manufactured by MEDICO-INSTRUMENT PLANT - MEDAPARAT, LIMITED LIABILITY COMPANY,

Zakhysnykiv Mykolayeva, 59-YU Street, city of Bilhorod-Dnistrovskyi, Odesa region, 67701, Ukraine, code USREOU (code United State Register of Enterprises and Organizations of Ukraine) 31411528,

according to the applicable regulatory documents of Ukraine

meets requirements of

ДСТУ EN ISO 13485:2018 «Медичні вироби. Система управління якістю.
Вимоги до регулювання»

N ISO 43485:2046 (ISO 43485:2046 idt) «Medical devices — Quality management eye

EN ISO 13485:2016 (ISO 13485:2016, idt) «Medical devices – Quality management systems – Requirements for regulatory purposes»

Monitoring of compliance of the certified Quality Management System with the requirements of the aforesaid standard is conducted through supervisory audit, whose periodicity and procedures are regulated by the Certificate Use Agreement

The certificate is considered valid subject to annual confirmation: in 2026 – till 28.02.2026, which is confirmed by the Decision.

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 basing on the findings

of the Quality Management System Audit.

Head of certification body of management systems

Andrii ANDRIUSHKO

SEAL 2 Kon 04725508

Validity of the Certificate may be verified at the State Enterprise "KHARKIVSTANDARTMETROLOGIYA", tel. +38 (057) 756-38-05, +38 (050) 753-14-00 or e-mail: 310@mtl.kharkov.ua