

UKRAINE

CERTIFICATION BODY OF MANAGEMENT SYSTEMS  
SE «KHARKOVSTANDARTMETROLOGY»

# CERTIFICATE

## OF QUALITY MANAGEMENT SYSTEM



80072  
Management  
systems certification

Registered in the Register  
of the Certification Body  
under No. UA80072.31411528.4-2024  
on February 29, 2024,

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, 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,

59 Maiakovskoho Street, city of Bilhorod-Dnistrovskyyi, 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»**

**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 2025 – till 28.02.2025 and 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 (Accreditation Certificate No.80072) basing on the findings of  
the Quality Management System Audit.

Head of certification body  
of management systems

Andriy ANDRYUSHKO

SEAL

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