

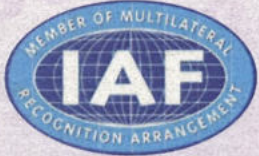
UKRAINE

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-Dnistrovskiy, 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