

UKRAINE
CERTIFICATION BODY OF MANAGEMENT SYSTEMS
SE «KHARKOVSTANDARTMETROLOGY»



80072
ISO/IEC 17021-1

CERTIFICATE
OF QUALITY MANAGEMENT SYSTEM

Registered in the Register
of the Certification Body
under No. UA80072.31411528.4-2021
on August 30, 2021,
Valid until August 29, 2024

This certificate hereby certifies that a quality management system in relation to
design and production air sterilizers and steam sterilizers, air thermostats,
PSSC (Products and Services State Classifier) codes 32.50.12-00.00, 26.51.70-15.00,
name of products, PSSC codes SC 016:2010

manufactured by **MEDICO-INSTRUMENT PLANT – MEDAPARAT, LIMITED LIABILITY COMPANY,**
59 Maiakovskoho Street, city of Bilhorod-Dnistrovskiyi, 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»**
**ISO 13485:2016 «Medical devices -- Quality management systems –
Requirements for regulatory purposes»**

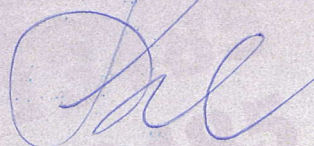
Monitoring of compliance of the certified Quality Management System with the requirements of the
aforesaid standard is conducted through supervisory audit, whose periodicity and procedures are
regulated by the Certificate Use Agreement

The certificate is considered valid subject to annual confirmation:
in 2022 - till 30.08.2022 and
in 2023 - till 30.08.2023,
which is confirmed by the Decision.

The Certificate is issued by the Management Systems Certification Body of State Enterprise "Kharkov
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.



Deputy head of certification body of
management systems


V. Agarkov



Validity of the Certificate may be verified
at the State Enterprise "Kharkovstandartmetrology", tel. +38 (057) 756-38-05