

UKRAINE

CERTIFICATION BODY OF MANAGEMENT SYSTEMS
SE «KHARKOVSTANDARTMETROLOGY»

CERTIFICATE OF QUALITY MANAGEMENT SYSTEM



80072
Management
systems certification

Registered in the Certification
Body Register

on August 16, 2024

№ UA80072.33574560.1-2024

Valid till August 15, 2027

This certificate is to certify that quality management system of the production of gels for functional diagnostics and treatment PSSC code 32.50.50-20.00 of DKPP DK 016:2010, recording thermal papers for medical devices (ECG, EEG, CTG, videoprinters, spirometers, autoclaves, laboratory printers, defibrillators and other medical devices in which the recording thermal papers are used) PSSC code 17.29.19-55.00 of DKPP DK 016:2010,

and service provision
for non-specialized wholesale trade, wholesale trade of pharmaceutical products
PSSC codes 46.90, 46.46 of DKPP DK 016:2010

which are produced by

Limited Liability Company «TVEL»,

36014, Ukraine, t. Poltava, str. Petra Doroshenka 57, code of SSREOU 33574560,

according to the existing regulation documents in Ukraine,
conforms to the requirements of

ДСТУ ISO 9001:2015 «Системи управління якістю. Вимоги»
(ISO 9001:2015 Quality management systems - Requirements, IDT),
ДСТУ EN ISO 9001:2018 «Системи управління якістю. Вимоги»
(EN ISO 9001:2015 Quality management systems - Requirements, IDT)

Control of conformity of the certified quality management system with the requirements of the specified standards is carried out through technical supervision, the frequency and procedure of which is regulated by the agreement.

Certificate is valid in case of annual audit:
in 2025 y. – till 16.08.2025 y. and in 2026 y. – till 16.08.2026 y.
which is confirmed by the Decision:

Certificate issued by the
management system certification body of the STATE ENTERPRISE «KHARKOV REGIONAL RESEARCH
AND PRODUCTION CENTRE FOR STANDARDIZATION, METROLOGY AND CERTIFICATION»,

36 Myronosytska str., Kharkiv city, Ukraine, 61002,
based on the results of the inspection and evaluation of the quality management system.

Head
of management systems
certification body



Andrii ANDRIUSHKO

UKRAINE

CERTIFICATION BODY OF MANAGEMENT SYSTEMS
SE «KHARKOVSTANDARTMETROLOGY»

CERTIFICATE

OF QUALITY MANAGEMENT SYSTEM



80072
DСТУ EN ISO/IEC 17021-1

Registered in the Register
of the Certification Body
"26" of December 2022 y.
№ UA80072.33574560.4-2022
Valid till "25" December 2025 y.

This certificate is to certify that quality management system of the production of

gels for functional diagnostics and treatment, code 32.50.50-20.00 of DKPP DK 016:2010, recording thermal papers for medical devices (ECG, EEG, CTG, videoprinters, spirometers, autoclaves, laboratory printers, defibrillators and other medical devices in which the recording thermal papers are used), code 17.29.19-55.00 of DKPP DK 016:2010,

which are produced by

Limited Liability Company «TVEL»,

36014, Ukraine, t. Poltava, str. Petra Doroshenka 57, code of SSREOU 33574560,

according to the existing regulation documents in Ukraine,
conforms to the requirements of

ISO 13485:2016 «Medical devices - Quality management systems - Requirements for regulatory purposes»,

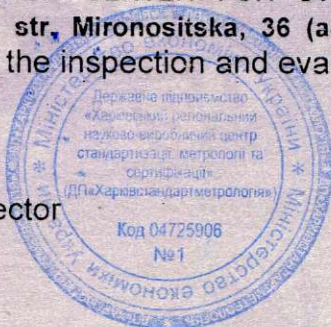
ДСТУ EN ISO 13485:2018 «Медичні вироби. Система управління якістю. Вимоги до регулювання»

Control of conformity of the certified quality management system with the requirements of the specified standard is carried out through technical supervision, the frequency and procedure of which is regulated by the agreement.

Certificate is valid in case of annual audit:
in 2023 y. – till 26.12.2023 y., in 2024 y. – till 26.12.2024 y.
which is confirmed by the Decision.

Certificate issued by the Certification Body of the State Enterprise "KHARKOV REGIONAL RESEARCH AND PRODUCTION CENTER FOR STANDARDIZATION, METROLOGY AND CERTIFICATION", 61002, Kharkiv, str. Mironositska, 36 (accreditation certificate No. 80072) based on the results of the inspection and evaluation of the quality management system.

Deputy Director
Seal



Victor AGARKOV

Validity of the Certificate can be checked in
SE "KHARKOVSTANDARTMETROLOGY" tel (057) 756-38-05