



10119
product
certification

CONFORMITY ASSESSING AUTHORITY
STATE ENTERPRISE "KHARKIV REGIONAL
RESEARCH AND PRODUCTION CENTER FOR STANDARDIZATION, METROLOGY AND CERTIFICATION"
(SE "KHARKIVSTANDARTMETROLOGIYA")

SERTIFICATE OF CONFORMITY

PROVISION OF FUNCTIONING OF COMPLEX QUALITY MANAGEMENT SYSTEM

(Technical regulations on medical devices, Annex 3, except for items 8-11)

№ UA.TR.002.CB.3485-24

Виробник MEDICO-INSTRUMENT PLANT – MEDAPARAT, LLC
59 Maiakovskoho Street, city of Bilhorod-Dnistrovskiy, Odesa region,
67701, Ukraine

Виробництво 59 Maiakovskoho Street, city of Bilhorod-Dnistrovskiy, Odesa region,
67701, Ukraine

Продукція Steam sterilizers: ГК-10, ГК-20,
risk class IIb according to Annex 2 of Technical regulation on medical
devices

Conformity assessing authority, "KHARKIVSTANDARTMETROLOGIYA" SE hereby states that the above manufacturer has implemented Quality Management System at the stages of development, manufacture and final testing of medical devices accordance to Annex 3, excluding paragraphs 8-11 of the Technical regulations on medical devices approved by Decree of the Cabinet of Ministers of Ukraine No. 753 as of 02/10/2013.

Manufacturer's Quality Management System complies with the appropriate provisions of Technical regulations on medical devices and subjects to regular control.

Project Verification Certificate is additionally required for distribution of III risk class devices at the market.

Звіт: 02/2024TR as of 19.02.2024 p.

Дата видачі: 01/04/2024

Дійсний до: 31/03/2029

Acting on a temporary basis
Deputy General Director for
Standardization



Mykola CHEREVATENKO

The validity of the certificate can be checked in the database of the Conformity assessment authority (khsms.com)

Conformity assessment body SE "KHARKIVSTANDARTMETROLOGIYA", legal address: 36 Myronosytska Str., Kharkiv, 61002, Ukraine 61002, tel. (057) 756 38 05. Appointed for assessment of conformity with the requirements of Technical regulations (order No. 204 dated 06/02/2020 of the Ministry of Economic of Ukraine, order of the Ministry of Economy No. 491 dated 10.03.2021 (expansion of the designation of the sphere), number of the appointed body UA.TR.002). Accredited by the National Accreditation Agency of Ukraine for assessment of product conformity and certification of Quality Management System (No.10119 and No.80072)