Hellenic Accreditation System

Annex A19/14 to the Certificate No. **58**-11

SCOPE OF ACCREDITATION

of

NATIONAL EVALUATION CENTER OF QUALITY AND TECHNOLOGY IN HEALTH CARE S.A.

as a Certification Body of Medical Devices Quality Management Systems in accordance with ELOT EN ISO 13485:2016

Main Technical Areas *(1)*	**Technical Areas** *(1)*
Non-active Medical Devices	General non-active, non-implantable medical device.
	Non-active implants.
	Devices for wound care.
	Non-active dental devices and accessories.
Active Medical Devices (Non-Implantable)	General active medical devices.
	Monitoring devices.
In Vitro Diagnostic Medical Devices	Reagents and reagent products, calibrators & control materials for: Clinical Chemistry. Immunochemistry (Immunology). Haematology/Haemostasis/Immunohematology. Microbiology. Infectious Immunology. Histology/Cytology. Genetic Testing.
	In Vitro Diagnostic Instruments and software.

Main Technical Areas [(1)]	**Technical Areas** [(1)]
In Vitro Diagnostic Medical Devices (con.)	IVD medical devices other than specified above: - Molecular biology products for the development of IVD medical devices - Tests for the molecular detection of SARS-COV-2 - Molecular biology products for laboratory use
Sterilization Method for Medical Devices	Ethylene oxide gas sterilization (EOG)
	Moist heat
	Aseptic processing
	Radiation sterilization (e.g. gamma, x-ray, electron beam)
Devices incorporating / utilizing specific substances / technologies	Medical devices incorporating medicinal substances.
	Medical devices utilizing nanomaterials.
	Medical devices utilizing biological active coatings and/or materials or being wholly or mainly absorbed.
	Medical devices incorporating / utilizing specific substances / technologies / elements, except for those specified in the other technical areas of the main technical area "Devices incorporating / utilizing specific substances / technologies".
Parts or services	Raw materials.
	Components.
	Subassemblies.
	Distribution services.
	Maintenance services.
	Transportation services.

[(1)] *According to IAF MD 8:2023.*

Address of the Body: **15 Mavrommation street, 10434 Athens, Greece**
Approved Signatory: **Eleftheria Pikrou**

This Scope of Accreditation replaces the previous one dated 26.02.2025.
The Accreditation Certificate No. **58**-11, according to ELOT EN ISO/IEC 17021-1:2015, is valid until 18.09.2029.

Athens, 16.09.2025

Konstantinou Evangelos Apostolos
CEO of ESYD