Hellenic Accreditation System

Annex A19/2 to the Certificate No. **3**-10

SCOPE OF ACCREDITATION

of

European Inspection and Certification Company (EUROCERT) S.A.

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

Main Technical Areas	**Technical Areas**[1]
Non-active Medical Devices	General non-active, non-implantable medical device
	Devices for wound care
	Non-active medical devices other than specified above: Examination Gloves Non-sterile Face Masks Incontinence Products Medical Earplugs
Active Medical Devices (Non-Implantable)	General active medical devices
	Monitoring devices
In Vitro Diagnostic Medical Devices (IVD)	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	Technical Areas[(1)]
Parts or services.	Components
	Distribution services
	Maintenance services
	Other services: Consulting services related to medical devices

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

Address of the Body : **89 Chlois Str & Likovrisis, 14452 Metamorfosi, Greece**
Approved Signatory : **George Briskolas, George Sifonios, Athi Xalkiopoulou.**

This Scope of Accreditation replaces the previous one, dated 30.10.2025.
The Accreditation Certificate No**.3-10** according to ELOT EN ISO/IEC 17021-1:2015 is valid until 29.11.2029.

Athens, 12.11.2025

Konstantinou Evangelos Apostolos
CEO of ESYD