Hellenic Accreditation System

Annex A19/**15** to the Certificate No. **236-9**

SCOPE OF ACCREDITATION

of

TÜV AUSTRIA HELLAS Ltd.

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 devices.
	Devices for wound care.
	Non-active medical devices except for those specified in the other technical areas of the main technical area “Non-active Medical Devices”.
	Non-active implants
	Non-active dental devices and accessories
Active Medical Devices (Non-Implantable).	General active medical devices.
In Vitro Diagnostic Medical Devices.	Software.
	In Vitro Diagnostic medical devices except for those specified in the other technical areas of the main technical area “In Vitro Diagnostic Medical Devices”.
	Reagents and reagent products, calibrators and control materials for: Clinical Chemistry Immunochemistry (Immunology) Haematology/Haemostasis/Immunohematology Microbiology Infectious Immunology Histology/Cytology Genetic Testing

Main Technical Areas [1]	Technical Areas [1]
Sterilization Method for Medical Devices	Aseptic Processing
Devices incorporating / utilizing specific substances / technologies.	Medical devices incorporating medicinal substances.
Parts or services.	Raw materials
	Components
	Subassemblies
	Maintenance services
	Distribution services
	Transportation services
	Other Services

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

Address of the Body: **429, Mesogion Avenue, Agia Paraskevi, 15343, Greece**
Approved Signatory: **Ioannis Kallias, ~~Charalabos Ageloudis~~, Rashid Mehr, Maria Agapitou, Yankı Ünal, Ana Vega.**

This Scope of Accreditation replaces the previous one dated **16.12.2024**.
The Accreditation Certificate No. **236-9**, according to ELOT EN ISO/IEC 17021-1:2015, is valid until **27.12.2029**.

Athens, **xx.xx.2025**

Konstantinou Evangelos Apostolos
CEO of ESYD