# Hellenic Accreditation System

Annex A19/14 to the Certificate No. **185**-10

# SCOPE OF ACCREDITATION

of

## TUV HELLAS 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. |
| | Non-active implants. |
| | Devices for wound care. |
| In Vitro Diagnostic Medical Devices | Reagents and reagent products, calibrators & control materials for:<br>Clinical Chemistry. |
| Parts or services. | Raw materials |
| | Distribution services |
| | Maintenance services |
| | Transportation services |
| | Other services: Consulting services related to medical devices, packaging services etc. |

| Main Technical Areas | Technical Areas[1] |
|---|---|
| Active Medical Devices (Non Implantable) | General active medical devices<br>Product Categories Covered by the Technical Areas: Software, including software design for medical devices |
| | Devices for imaging.<br>Product Categories Covered by the Technical Areas:<br>Devices utilizing non-ionizing radiation |
| Sterilization Method for Medical Devices | Ethylene oxide gas sterilization (EOG) |

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

Address of the Body : **282, Mesogeion Av., 155 62 Cholargos, Athens, Greece**
Approved Signatory : **M. Kypriotou, G. Melachroinos, T. Giannouli.**

This Scope of Accreditation replaces the previous one, dated 28.04.2025.
The Accreditation Certificate No.185-10 according to ELOT EN ISO/IEC 17021-1:2015 is valid until 04.11.2029.

Athens, 20.10.2025

Konstantinou Evangelos Apostolos
CEO of ESYD