Hellenic Accreditation System

Annex B4/1 to the Certificate No. **1309**

SCOPE of ACCREDITATION

of the

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

as a Products Certification Body
in accordance with E.C. Directives

Field of Certification	Type of certification	Normative Regulations / Standards / In-House Procedures
Medical devices Non-active Medical Devices [(1)] - General non-active, non-implantable medical devices. - Non-active implants. - Devices for wound care. - Non-active dental devices and accessories.		Regulation (EU) 2017/745 Regulation (EU) 2020/561 ELOT EN ISO 13485:2016 +A11:2021
Active Medical Devices (Non-Implantable) [(1)] - General active medical devices. - Devices for imaging. - Monitoring devices. - Devices for radiation therapy and thermo therapy.	- Quality Management System and Technical Documentation assessment - Production quality assurance including Technical Documentation Assessment	Regulation (EU) 2017/745 – Annex IX Regulation (EU) 2017/745 – Annex XI, Part A
Devices incorporating / utilizing specific substances / technologies [(1)] - 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".		

[(1)] *Technical areas according to IAF MD 8:2020.*

Address of the Body: **10, Stadiou & 4, Omirou street, 10 564 Athens, Greece**
Approved signatory: **Eleftheria Pikrou**

The Accreditation Certificate No. **1309**, according to ELOT EN ISO/IEC 17065:2012, is valid until 20.09.2026 according to ESYD decision, which was validated on 19.09.2022.

Athens, 21.09.2022

Christos Nestoras
CEO of ESYD