Hellenic Accreditation System

Annex A19/**13** to the Certificate No. 248-**8**

SCOPE OF ACCREDITATION

of

DQS HELLAS Ltd

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

Main Technical Areas	Technical Areas
Non-active Medical Devices	General non-active, non-implantable medical device.
	Devices for wound care.
	Non-active dental devices and accessories.
	Non-active medical devices except for those specified in the other technical areas of the main technical area "Non-active Medical Devices".
Active Medical Devices (Non-Implantable)	Monitoring devices.
	Active (non-implantable) medical devices except for those specified in the other technical areas of the main technical area "Active Medical Devices (Non-Implantable)".
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
	In Vitro Diagnostic Instruments and software

Main Technical Areas	Technical Areas
	In Vitro Diagnostic medical devices except for those specified in the other technical areas of the main technical area "In Vitro Diagnostic Medical Devices".
Parts or Services	Raw materials.
	Components.
	Subassemblies
	Distribution services.
	Maintenance services.
	Transportation services.

[(1)] *According to IAF MD 8:2020.*

Address of the Body: **2, Kalavriton St., 145 64 Kifisia, Athens**
Approved signatory: **E. Deligiannakis**

This Scope of Accreditation replaces the previous one dated **13.12.2023**.
The Accreditation Certificate No.248-**8**, according to ELOT EN ISO/IEC 17021-1:2015 is valid until **20.05.2025**.

Athens, **19.09.2024**

Konstantinos Kourtalis
Chairman of ESYD