



EU Quality Management System Certificate

Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapter I

Certificate No. V13 109710 0003 Rev. 00

Manufacturer:

Chema Diagnostica Srl

Via Campania 2/4
60030 Monsano AN
ITALY

SRN Manufacturer - IT-MF-000009128

The quality management system has been evaluated in accordance with Regulation (EU) 2017/746, Annex IX Chapter I with a positive result.

Details on devices covered by the quality management system are described on the following page(s). The report referenced below summarises the results of the assessment and includes reference to relevant CS, harmonised standards and test reports.

The certified quality management system is subject to periodical surveillance.

If class A devices in sterile conditions are covered by this certificate, the audit was limited to the aspects relating to establishing, securing, and maintaining sterile conditions.

If class B or C excluding self-/near-patient-testing, or class C companion diagnostics devices are covered by this certificate, the quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis. The periodical surveillance includes further assessment of the technical documentation on the basis of representative samples.

If class D devices, class B or C self-/near-patient testing, or class C companion diagnostics devices are covered by this certificate, an EU Technical Documentation Assessment Certificate in accordance with Annex IX Chapter II is required before placing them on the market.

All applicable requirements of the Testing, Certification, Validation and Verification Regulations TÜV SÜD Group have to be complied with.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:V13 109710 0003 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:V13_109710_0003_Rev.00)

Report No.: ITA200220016814_CN
Preceding Certificate No.: V12 109710 0002 Rev. 00

Valid from: 2026-02-19
Valid until: 2027-06-26

Marta Carnielli
Head of Certification IVD

Issue date: 2026-02-19



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Classification: Class C
Device Group: W0102 + IVP 3007 - Immunochemistry
Intended Purpose: IVD Reagents for Immunochemistry

Classification: Class C
Device Group: W0101 + IVP 3002 - Clinical chemistry
Intended Purpose: IVD Reagent products for clinical chemistry

Classification: Class B
Device Group: IVR 0608 - Physiological status and therapeutic measures:
 General physiological markers
Intended Purpose: Devices intended to be used for screening, determination or
 monitoring of physiological markers

The validity of this certificate \ depends on conditions and/or is limited to the following:

Revision History:

Rev.	Dated	Report	Description
00	2026-02-19	ITA200220016814_CN	Administrative merge / transfer to new Certificate Type