



EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices,
Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and
Companion Diagnostics)

No. V12 109710 0002 Rev. 00

Manufacturer: **Chema Diagnostica Srl**
Via Campania 2/4
60030 Monsano AN
ITALY

SRN Manufacturer: IT-MF-000009128

The Certification Body of TÜV SÜD Product Service GmbH certifies that the manufacturer has established, documented and implemented a quality management system as described in Article 10 (8) of the Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices. Details on devices covered by the quality management system are described on the following page(s).

The Report referenced below summarizes the result of the assessment and includes reference to relevant CS, harmonized standards, audit and test reports. The conformity assessment has been carried out according to Annex IX Chapter I and III of this regulation with a positive result.

The quality management system assessment was accompanied by the assessment of technical documentation for devices selected on a representative basis.

The certified quality management system is subject to periodical surveillance by TÜV SÜD Product Service GmbH. The surveillance assessment includes an assessment of the technical documentation for the device or devices concerned on the basis of further representative samples.

For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:V12 109710 0002 Rev. 00](http://www.tuvsud.com/ps-cert?q=cert:V12_109710_0002_Rev.00)

Report No.: ITA1691790

Valid from: 2022-06-27

Valid until: 2027-06-26

Christoph Dicks
Head of Certification/Notified Body

Issue date: 2022-06-27



EU Quality Management System Certificate (IVDR)

Pursuant to Regulation (EU) 2017/746 on in Vitro Diagnostic Medical Devices, Annex IX Chapters I and III (Class C and B Devices excluding self-/near-patient-testing and Companion Diagnostics)

No. V12 109710 0002 Rev. 00

Classification: C
Device Group: W0102 - IMMUNOCHEMISTRY (IMMUNOLOGY)
IVP Code: IVP 3007 - In vitro diagnostic devices which require knowledge regarding immunoassays
Intended Purpose: IVR 0506 - Other devices intended to be used to determine markers of infections/immune status

Classification: C
Device Group: W0101 - CLINICAL CHEMISTRY
IVP Code: IVP 3002 - In vitro diagnostic devices which require knowledge regarding biochemistry
Intended Purpose: IVR 0608 - Devices intended to be used for screening, determination or monitoring of physiological markers

Classification: B
Device Group: W0101 - CLINICAL CHEMISTRY
Intended Purpose: IVR 0608 - 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: \