



EC Certificate

Full Quality Assurance System

Directive 98/79/EC on In Vitro Diagnostic Medical Devices (IVDD), Annex IV excluding (4, 6)
(List A and B and devices for self-testing)

No. V1 057136 0014 Rev. 01

Manufacturer: **Chromsystems
Instruments & Chemicals GmbH**
Am Haag 12
82166 Gräfelfing
GERMANY

Facility(ies): Chromsystems Instruments & Chemicals GmbH
Am Haag 12, 82166 Gräfelfing, GERMANY

Product Category(ies): **Products for determination of Phenylketonuria**

Model(s): **Reagents, calibrators, controls, and accessories
for Tandem Mass Spectrometry (LC-MS/MS)
of amino acids and acyl carnitines for
newborn screening and for the quantitative
determination of amino acids, in particular in
metabolic diseases**

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device families in accordance with IVDD Annex IV. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of List A devices an additional Annex IV (4) certificate is mandatory. All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:V1 057136 0014 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:V1_057136_0014_Rev.01)

Report no.: 713228082

Valid from: 2022-03-16

Valid until: 2025-05-26

Date, 2022-03-16

Christoph Dicks
Head of Certification/Notified Body