



Product Service

# 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 17 04 57136 011

**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, controls, and accessories for  
Tandem Mass Spectrometry (LC-MS/MS)  
of amino acids and acyl carnitines for  
newborn screening**

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. See also notes overleaf.

**Report no.:**

713097868

**Valid from:**

2017-05-18

**Valid until:**

2022-05-17



**Date,** 2017-04-28

Stefan Preiß

TÜV SÜD Product Service GmbH is Notified Body with identification no. 0123

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