

## EC-Declaration of Conformity

according to directive 98/79 EC on in vitro diagnostic medical devices

We, as manufacturer

Chromsystems Instruments & Chemicals GmbH  
Am Haag 12  
82166 Gräfelfing, Germany

declare on our own responsibility, that herein after called in vitro diagnostic medical devices for the LC-MS/MS determination of:

GMDN Code und Name: 64602 "Multiple amino acid IVD, kit, liquid chromatography/mass spectrometry (LC/MS)"

EDMA Nomenclature term: Phenylketonuria

EDMA Nomenclature code: 11-02-01-36-00

IVDD Classification: Annex II, List B

Reagent Kit: **75111 - MassChrom® Amino Acid Analysis in plasma/serum**

**75111/DWP - MassChrom® Amino Acid Analysis in plasma/serum**

Calibrator: **75128 – 3PLUS1® Multilevel Plasma Calibrator Set**

Controls: **0471 - MassCheck® Amino Acid Analysis Control Level I**

**0472 - MassCheck® Amino Acid Analysis Control Level II**

**0473 - MassCheck® Amino Acid Analysis Control Level III**

### Components / Accessories

75001	Mobile Phase A
75002	Mobile Phase B
75009	Rinsing Solution
75146	Internal Standard Set
75105	Precipitation Reagent
75100	Analytical Column
75058	Collection Plate
75060	Pierceable Heat Seals, for 96 well plates
75156	96 Deep Well Plates
75010	System Check Solution
75015	Tuning Mix 1
75016	Tuning Mix 2
75017	Tuning Mix 3
75018	Tuning Mix 4
75019	Tuning Mix 5

EC declaration valid until May 26<sup>th</sup>, 2025

Vers. 2.0  
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Meets all applicable requirements of the directive 98/79/EC

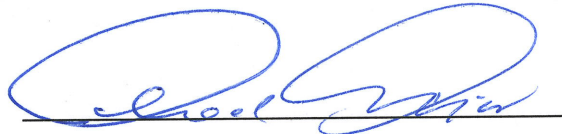
The conformity was proved by the conformity assessment procedures referred to Annex IV directive 98/79/EC, excluding section 4 & 6

The application for screening of PKU (98/79/EG Annex II List B) was subject to conformity assessment according to Annex IV (excluding section 4 & 6) under the participation of the following notified body:

**TÜV SÜD Product Service GmbH (identification number 0123)**  
**Medical Health Service / In Vitro Diagnostic**  
**Ridlerstr. 65**  
**80339 Munich, Germany**

The corresponding certificate is maintained.

Gräfelfing, May 02<sup>nd</sup>, 2022



Michael Meier, Managing Director