CHROMSYSTEMS
DIAGNOSTICS BY HPLC & LC-MS/MS

# Addendum to

# 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 / Acessories

| | |
|---|---|
| 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, for96 well plates |
| 75156 | 96 Deep Well Plates |
| 75010 | System Check Solution |
| 75015 | Tuning Mix 1 |
| 75016 | Tuning Mix 2 |
| 75017 | Tuning Mix 3 |

EC declaration valid until December 31th, 2027



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| | |
|---|---|
| 75018 | Tuning Mix 4 |
| 75019 | Tuning Mix 5 |

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.

Originally issued May 02nd, 2022 V2.0 is still valid until December 31th, 2027 according to regulation (EU) 2024/1860.

Gräfelfing, April 14th, 2025

Michael Meier, Managing Director



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