CHROMSYSTEMS
DIAGNOSTICS BY HPLC & LC-MS/MS

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:	60444 Newborn metabolic screen/congenital disorder IVD, kit, mass spectrophotometry
EDMA Nomenclature term:	Phenylketonuria
EDMA Nomenclature code:	11-02-01-36-00
EDMA Classification:	*Annex II, List B*

Reagent Kit: **55000 - *MassChrom*® Amino Acids and Acylcarnitines from Dried Blood**
55000/F - *MassChrom*® Amino Acids and Acylcarnitines from Dried Blood
55111 - Succinylacetone Upgrade Set

Controls: **0191 - *MassCheck*® Amino Acids, Acylcarnitines incl. Succinylacetone Dried Blood Spot Control Bi-Level (I + II)**

0192 - *MassCheck*® Amino Acids, Acylcarnitines incl. Succinylacetone Dried Blood Spot Control Level I

0193 - *MassCheck*® Amino Acids, Acylcarnitines incl. Succinylacetone Dried Blood Spot Control Level II

Components / Accessories:

55001	Mobile Phase
55002	Mobile Phase (10x)
55004	Internal Standard, lyophilised
55044	Internal Standard Succinylacetone
55005	Derivatisation Reagent
55006	Reconstitution Buffer
55007	Rinsing Solution
55008	Extraction Buffer
55010	96 Well plates
55010/F	96 Well plates
55011	Protective sheets for 96 well plates
57014	Pierceable Heat Seals for 96 well plates

EC declaration valid until May 26th, 2025

Vers. 6.0

55057	96 Well filter plates
55111	Succinylacetone Upgrade Set
55013	Piercable Adhesive Seals for 96 well plates
55015	Restrictor Capillary
55016	Adapter Collar for centrifugation
55098	Tuning Mix Succinylacetone
55099	Tuning Mix (incl. all analytes)

Meets all applicable requirements of the directive 98/79/EC

The conformity was proven by the conformity assessment procedures referred to Annex IV of 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 (notified body number 0123)
Medical Health Service / In Vitro Diagnostic
Ridlerstr. 65
80339 Munich, Germany

The corresponding certificate of notified body is maintained.

Gräfelfing, April 28th, 2022

Michael Meier, Managing Director

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