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:	66044 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*

Product name: **57000 *MassChrom*® Amino Acids and Acylcarnitines from Dried Blood (non derivatised)**

57000/F *MassChrom*® Amino Acids and Acylcarnitines from Dried Blood (non derivatised)

57111 Succinylacetone (non derivatised) Upgrade Set

57111/F Succinylacetone (non derivatised) 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

57001	Mobile Phase
57002	Mobile Phase (10x)
57004	Internal Standard

EC declaration valid until May 26th, 2025

Vers. 6.1

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57004/FR	Internal Standard
57044	Internal Standard, Succinylacetone (non derivatised)
57007	Rinsing Solution
57008	Extraction Buffer
57012	Extraction Buffer, Succinylacetone (non derivatised)
57010	96 Well Plates
55011	Protective Sheets for 96 Well Plates
57057	96 Well Filter Plates
57015	Cross-cut Adhesive Seals for 96 Well Plates
57014	Pierceable Heat Seals for 96 Well Plates
55015	Restrictor Capillary
57098	Tuning Mix, Succinylacetone (non derivatised)
57099	Tuning Mix

meet 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, May 16th, 2022

Michael Meier
Managing Director

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