

Addendum to

EC-Declaration of Conformity

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

Reagent Kit: **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
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

Originally issued May 16th, 2022 V6.1 is still valid until December 31th, 2027 according to regulation 2024/1860

Gräfelfing, November 15th, 2024



Michael Meier, Managing Director

EC declaration valid until December 31th, 2027

Vers. 1.0