

## Addendum to

## EC-Declaration of Conformity

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

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**

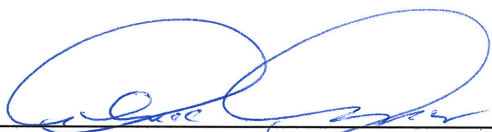
**0193 - MassCheck® Amino Acids, Acylcarnitines incl. Succinylacetone**  
**Dried Blood Spot Control Level II**

### 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
55057	96 Well filter plates
55111	Succinylacetone Upgrade Set
57014	Pierceable Heat Seals for 96 well plates
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)

Originally issued April 28<sup>th</sup>, 2022 V6.0 is still valid until December 31<sup>th</sup>, 2027  
according to regulation 2024/1860

Gräfelfing, November 15<sup>th</sup>, 2024



Michael Meier, Managing Director

EC declaration valid until December 31<sup>th</sup>, 2027

Vers. 1.0