

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 HPLC determination of:

Reagent Kit: **43000 - Hippuric Acid, Methylhippuric Acids, Mandelic Acid and Phenylglyoxylic Acid in Urine**

Covers all calibrators, controls and components/accessories as listed on EC-Declaration of conformity V5.0 valid since May 02nd, 2022

The following devices have been introduced:

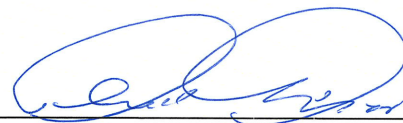
43043	Hippuric Acid, Methylhippuric Acids, Mandelic Acid and Phenylglyoxylic Acid in Urine
43011	Mobile Phase
18010	Precolumn Cartridge 4/10

And meet all applicable requirements of the directive 98/79/EC and the conformity assessment procedure: Annex III of the directive 98/79/EC

The originally issued certificate is still valid until December 31th, 2029 according to regulation 2024/1860

Notified body: -

Gräfelfing, April 01st, 2026



Michael Meier, Managing Director