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 60668, term "Ethyl glucuronide (EtG) IVD, kit, mass spectrometry"

EDMA Nomenclature term:	Ethyl Glucuronide
EDMA Nomenclature code:	12-09-02-20-00
IVDD Classification:	other product

Reagent Kit: 69000 – ***MassChrom***® Ethyl Glucuronide, Ethyl Sulfate in Urine

Calibrators: 69039 – **6PLUS1**® Multilevel Calibrator Set

Controls:
0367 - ***MassCheck***® Ethyl Glucuronide, Ethyl Sulfate Urine Control Level I
0368 - ***MassCheck***® Ethyl Glucuronide, Ethyl Sulfate Urine Control Level II
0369 - ***MassCheck***® Ethyl Glucuronide, Ethyl Sulfate Urine Control Level III

Products:
69001 - Mobile Phase A
69002 - Mobile Phase B
69004 - Internal Standard Mix
69005 - Dilution Buffer
69009 - Rinsing Solution
69100 - HPLC Column
69012 - System Check Solution
69015 - Tuning Mix

meet all applicable requirements of the directive 98/79/EC.

Conformity assessment procedure: Annex III of the directive 98/79/EC

EC declaration valid until May 26th, 2027

Vers. 4.0

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Applied harmonized standards:

EN ISO 13485, EN 13612, EN 13641, EN ISO 14971, EN 18113-1, EN 18113-2, EN 15223-1, EN 17511, EN 23640

Notified body: –

Gräfelfing, May 02nd, 2022

Michael Meier, Managing Director

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