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 HPLC determination of:

GMDN Code 63822, term "Multiple-therapy therapeutic drug monitoring IVD, kit, liquid chromatography"

EDMA Nomenclature term:	Other Antibiotics TDM
EDMA Nomenclature code:	12-08-03-90-00
IVDD Classification:	*other product*

Reagent Kit: 61000 – Antibiotics in serum/plasma

Calibrators: 61028 – 3PLUS1® Multilevel Plasma Calibrator Set Antibiotics in serum/plasma
61003 – Plasma Calibration Standard Antibiotics in serum/plasma

Controls: 0183 – Plasma Control Level I, Antibiotics in serum/plasma
0184 – Plasma Control Level II, Antibiotics in serum/plasma

Products:

61001 - Mobile Phase A
61002 - Mobile Phase B
61004 - Internal Standard Mix
61005 - Dilution Buffer
61012 - Priming Solution
61100 - Analytical Column
18061 - Precolumn cartridge 4/10

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

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

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

EC declaration valid until May 26th, 2027

Vers. 3.0

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Notified body: –

Gräfelfing, May 02nd, 2022

Michael Meier, Managing Director

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