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 63821, term "Multiple antimicrobial therapeutic drug monitoring IVD, kit, liquid chromatography"

EDMA Nomenclature term:	Other Other Clinical Chemistry Reagents
EDMA Nomenclature code:	11-90-01-90-00
IVDD Classification:	*other product*

Reagent Kit: **27037 - Itraconazole, Posaconazole, Voriconazole in serum/plasma**

Calibrators:
27034 - Plasma Calibration Standard
27029 - 3PLUS1® Multilevel Calibrator Set

Controls:
0330 - Plasma Control Tri-Level (I+II+III)
0331 - Plasma Control Level I
0332 - Plasma Control Level II
0333 - Plasma Control Level III

Products:
27021 - Mobile Phase
27022 - Mobile Phase (10x)
27044 - Internal Standard
27055 - Precipitation Reagent 1
27066 - Precipitation Reagent 2
27110 - HPLC column
18027 - 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

EC declaration valid until May 26th, 2027

Vers. 4.0

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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