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 64465, term "Mycophenolate therapeutic drug monitoring IVD, kit, liquid chromatography"

EDMA Nomenclature term:	Mycophenolate
EDMA Nomenclature code:	*12-08-06-05-00*
IVDD Classification:	*other product*

Reagent Kit: 46000 – Mycophenolic Acid in plasma/serum

Calibrators: 46003 – Plasma Calibration Standard
46029 – 3PLUS1® Multilevel Plasma Calibrator Set

Controls: 0041 – Plasma Control Bi-Level (I+II)
0042 – Plasma Control Level I
0043 – Plasma Control Level II

Products:

46012/HR - Mobile Phase, HIGH RESOLUTION
46004 - Internal Standard
46005 - Equilibration Buffer 1
46006 - Equilibration Buffer 2
46007 - Wash Buffer
46009 - Elution Buffer
46008 - Sample Clean Up Columns
46110/HR - HPLC Column
17046 - 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, 2026

Vers. 5.0

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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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