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 61998, term "Mycophenolate therapeutic drug monitoring IVD, kit, liquid chromatography/mass spectrometry (LC/MS)"

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

Reagent Kit: 92716 - ***MassTox***® TDM Series A PARAMETER-Set
Mycophenolic Acid in Serum/Plasma
For automated sample preparation on Hamilton MassSTAR

Calibrators: 46029 – 3PLUS1® Multilevel Plasma Calibrator Set
Mycophenolic Acid / Glucuronide

Controls: 0234 - ***MassCheck***® Mycophenolic Acid / Glucuronide
Plasma Control, Bi-Level (I + II)

0235 - ***MassCheck***® Mycophenolic Acid / Glucuronide
Plasma Control, Level I

0236 - ***MassCheck***® Mycophenolic Acid / Glucuronide
Plasma Control, Level II

Products:
92246 - Internal Standard Set Mycophenolic Acid
92019 - Tuning Mix Mycophenolic Acid

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, 2026

Vers. 1.0

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Notified body: –

Gräfelfing, May 16th, 2022

Michael Meier, Managing Director

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