

## Addendum to 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

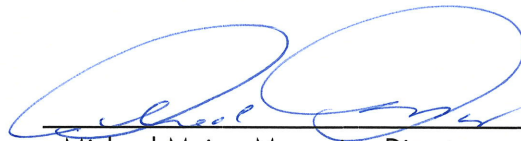
Applied harmonized standards:

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: -

Originally issued May 02<sup>nd</sup>, 2022 V4.0 is still valid until December 31<sup>th</sup>, 2028 according to regulation (EU) 2024/1860.

Gräfelfing, July 02<sup>nd</sup>, 2026



Michael Meier, Managing Director

EC declaration valid until December 31<sup>th</sup>, 2028

Addendum Vers. 1.0  
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