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

Reagent Kit: **26000 - Olanzapine, Desmethylolanzapine in Serum/Plasma**

Calibrator:
26003 - Plasma Calibration Standard
Olanzapine, Desmethylolanzapine in serum/plasma
28007 - Plasma Calibration Standard
Perazine, Quetiapine, Citalopram

Controls:
0147 - Plasma Control, Bi-Level (I+II)
Olanzapine, Desmethylolanzapine in serum/plasma
0148 -Plasma Control, Level I
Olanzapine, Desmethylolanzapine in serum/plasma
0149 - Plasma Control, Level II
Olanzapine, Desmethylolanzapine in serum/plasma
0131 - Plasma Control, Bi-Level (I+II)
Perazine, Quetiapine, Citalopram
0132 -Plasma Control, Level I
Perazine, Quetiapine, Citalopram
0133 - Plasma Control, Level II
Perazine, Quetiapine, Citalopram

Products:
26001 - Mobile Phase
26004 - Internal Standard
26005 - Equilibration Buffer 1
26006 - Equilibration Buffer 2
26009 - Wash Buffer

EC declaration valid until May 26th, 2027

Vers. 3.0

CHROMSYSTEMS
DIAGNOSTICS BY HPLC & LC-MS/MS

26010 – Elution Buffer
26008 – Sample Clean Up Columns
26100 – HPLC column
18026 – 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: –

Gräfelfing, May 02nd, 2022

Michael Meier, Managing Director

EC declaration valid until May 26th, 2027

Vers. 3.0

Chromsystems
Instruments & Chemicals GmbH
Am Haag 12
82166 Gräfelfing/Germany
Telefon: +49 89 18930-0
Telefax: +49 89 18930-199
mailbox@chromsystems.com
www.chromsystems.com