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:	Benzodiazepine
EDMA Nomenclature code:	12-09-01-04-00
IVDD Classification:	*other product*

Reagent Kits:
- 49000 - Benzodiazepines and Tricyclic Antidepressants in Serum/Plasma
- 49000/A1 - Benzodiazepines/Tricyclic Antidepressants in Serum/Plasma - automated HPLC
- 49000/A5 - Benzodiazepines/Tricyclic Antidepressants in Serum/Plasma - automated HPLC
- 49000/A9 - Benzodiazepines/Tricyclic Antidepressants in Serum/Plasma - automated HPLC

Calibrators:
- 49003 – Plasma Calibration Standard (BZD + TCA)
- 49031 – Plasma Calibration Standard (BZD)
- 49032 – Plasma Calibration Standard (TCA)
- 49033 - Clozapine, Norclozapine Plasma Calibration Standard
- 49034 - Clobazam, Norclobazam Plasma Calibration Standard
- 49035 - Alprazolam, Trazodone Plasma Calibration Standard

Controls:
- 0051 - Benzodiazepines Plasma Control Bi-Level
- 0052 - Benzodiazepines Plasma Control Level I
- 0053 - Benzodiazepines Plasma Control Level II
- 0054 - Tricyclic Antidepressants Plasma Control Bi-Level
- 0055 - Tricyclic Antidepressants Plasma Control Level I
- 0056 - Tricyclic Antidepressants Plasma Control Level II
- 0057 - Clozapine, Norclozapine Plasma Control Bi-Level (I + II)
- 0057/1 - Clozapine, Norclozapine Plasma Control Level I
- 0057/2 - Clozapine, Norclozapine Plasma Control Level II

EC declaration valid until May 26th, 2027

Vers. 4.0

Chromsystems
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0061 - Clobazam, Norclobazam Plasma Control Bi-Level (I + II)
0061/1 - Clobazam, Norclobazam Plasma Control Level I
0061/2 - Clobazam, Norclobazam Plasma Control Level II
0062 - Alprazolam, Trazodone Plasma Control Bi-Level (I + II)
0062/1 - Alprazolam, Trazodone Plasma Control Level I
0062/2 - Alprazolam, Trazodone Plasma Control Level II

Products:

49001 - Mobile Phase
49001/II - Mobile Phase Benzodiazepines II
49002 - Mobile Phase (10x)
49004 - Internal Standard
49004/A1 - Internal Standard
49004/A9 - Internal Standard
49041- Internal Standard Clozapine/Norclozapine
49044 – Internal Standard TCA
49044/A9 – Internal Standard TCA
49005 - Equilibration Buffer 1
49005/A1 - Equilibration Buffer 1
49005/A5 - Equilibration Buffer 1
49005/A9 - Equilibration Buffer 1
49006 - Equilibration Buffer 2
49006/A1 - Equilibration Buffer 2
49006/A5 - Equilibration Buffer 2
49006/A9 - Equilibration Buffer 2
49007 - Wash Buffer
49007/A1 - Wash Buffer
49007/A9 - Wash Buffer
49009 - Elution Buffer 1
49009/A1 - Elution Buffer 1
49009/A5 - Elution Buffer 1
49010 - Elution Buffer 2
49010/A1 - Elution Buffer 2
49010/A5 - Elution Buffer 2
49008 - Sample Clean Up Columns
49008/A - Sample Clean Up Columns
49100 - HPLC column
17049 - 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

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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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