

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

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

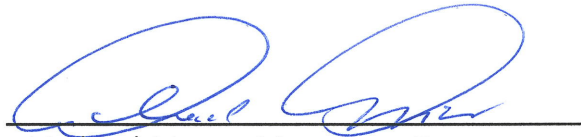
EC declaration valid until May 26th, 2027

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

