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 62050, term "Coenzyme Q10 (CoQ10) 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: 68000 - Coenzyme Q10 in Serum/Plasma/Whole Blood

Calibrator: 68003 – Plasma Calibration Standard

Controls:
0091 - Plasma Control Bi-Level (I+II)
0092 - Plasma Control Level I
0093 - Plasma Control Level II

Products:
68001 - Mobile Phase
68002 – Mobile Phase (10x)
68004 - Internal Standard
68005 - Precipitation Reagent 1
68006 - Precipitation Reagent 2
68007 - Wash Buffer 1
68008 - Sample Clean Up Columns
68009 - Wash Buffer 2
68010 - Elution Buffer
68100 - HPLC column
18068 - 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

Vers. 4.0

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

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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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