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: 53628, term "Carbohydrate deficient transferrin IVD, kit, liquid chromatography"

EDMA-Nomenclature term: Carbo Hydrate Deficient Transferrin
EDMA-Nomenclature code: 12-12-01-02-00
IVDD Classification: *other product*

Reagent Kit:

54020 – CDT in serum for binary gradient

54020/500 – CDT in serum binary gradient

54030 – CDT in serum for ternary gradient

54030/500 – CDT in serum for ternary gradient

54330/500 – CDT FE in serum for ternary gradient systems Fast Elution

54730/F – CDT in serum, automated using 96 well filter plates / Fast Elution

54930/500 – One Step CDT in Serum Fast Elution

Controls:

0168 – Serum Control Level I

0169 – Serum Control Level II

Products:

54021	Mobile Phase A
54022	Mobile Phase B
54025	Neutralisation Buffer
54026	Stabilisation Buffer
54027	Precipitation Reagent 1
54028	Precipitation Reagent 2
54029	Column Wash Buffer
54031	Mobile Phase A
54032	Mobile Phase B
54033	Mobile Phase C
54331	Mobile Phase A

EC declaration valid until May 26th, 2027

Vers. 5.0

54332	Mobile Phase B
54333	Mobile Phase C
54931	Mobile Phase A (Fast Elution)
54932	Mobile Phase B (Fast Elution)
54933	Mobile Phase C (Fast Elution)
54934	Pre-mixed Tubes
54757	96 Well Filter Plates
54758	96 Well Collection Plates
54759	Pierceable Adhesive Seals
54100	HPLC column

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 16th, 2022

Michael Meier, Managing Director

EC declaration valid until May 26th, 2027

Vers. 5.0

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