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:

Nomenclature term: Thalassaemia
Nomenclature code: 16-01-01-11-00
IVDD Classification: other product

Product name: **15440 – ß-Thalassemia Screening**

Components / Accessories for Catecholamines in Plasma

15441	Buffer A
15441/C	Buffer A
15442	Buffer B
15442/C	Buffer B
15444	Hemolysis Reagent
15445	Wash Buffer
15490	HPLC Column
15007/B	Reaction Vials

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

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