

## 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 –  $\beta$ -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.

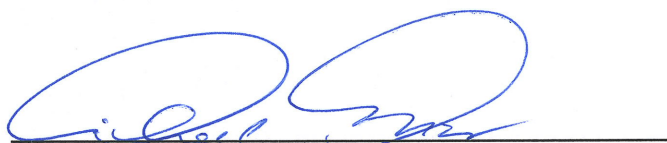
Conformity assessment procedure: Annex III of the directive 98/79/EC

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 16<sup>th</sup>, 2022



Michael Meier, Managing Director

EC declaration valid until May 26<sup>th</sup>, 2027

Vers. 3.0  
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