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 53313, term „Glycated haemoglobin (HbA1c) IVD, kit, liquid chromatogaphy

Nomenclature term: Haemoglobin subtypes HbA2,HbC,HbF,HbS,etc.(excl. HbA1)
Nomenclature code: 13-01-02-02-00
IVDD Classification: *other product*

Product name: **15330 – Hemoglobin Variants**

Components / Accessories for Catecholamines in Plasma

15331	Buffer A
15331/C	Buffer A
15332	Buffer B
15332/C	Buffer B
15334	Hemolysis Reagent
15335	Wash Buffer
15390	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

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Managementsystem zertifiziert nach:
ISO 9001, ISO 13485 (including MDSAP)