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 55481, term "Amiodarone IVD, kit, liquid chromatography"

EDMA Nomenclature term:	Other Cardiovascular TDM
EDMA Nomenclature code:	12-08-01-90
IVDD Classification:	*other product*

Reagent Kit: **25000 - Amiodarone, Desethylamiodarone in Serum/Plasma**

Calibrator: **25005 - Plasma Calibration Standard**

Controls: **0067 – Plasma Control Level I**
0068 – Plasma Control -Level II

Products:

25011 - Mobile Phase
25022 - Mobile Phase (10x)
25033 - Precipitation Reagent
25044 - Internal Standard
25100 - HPLC column
18025 - 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

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

EC declaration valid until May 26th, 2027

Vers. 4.0