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 LC-MS/MS determination of:

GMDN code: 63849, term "Free cortisol/cortisone IVD, kit, liquid chromatography/ mass spectrometry (LC/MS)"

EDMA Nomenclature term:	Cortisol
EDMA Nomenclature code:	12-06-02-04-00
IVDD Classification:	*general IVD, other product*

Reagent Kit:	73000 - ***MassChrom®*** Cortisol, Cortisone in saliva
Calibrator:	73040 - 6PLUS1® Multilevel Saliva Calibrator Set ***MassChrom®*** Cortisol, Cortisone in saliva
Controls:	0353 - ***MassCheck®*** Cortisol, Cortisone Saliva Control Level I 0354 - ***MassCheck®*** Cortisol, Cortisone Saliva Control Level II
Products:	73001 - Mobile Phase A 73002 - Mobile Phase B 73004 - Internal Standard Mix 73008 - Clean-Up Tubes 73009 - Rinsing Solution 73015 - Tuning Mix 72088 - System Check Solution ***MassChrom®*** Steroids Panel 1 73100 - Analytical 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 05th, 2022

Michael Meier, Managing Director

EC declaration valid until May 26th, 2026

Vers. 1.0