

Addendum

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: 73039 - 6PLUS1[®] Multilevel Saliva Calibrator Set
MassChrom[®] Cortisol, Cortisone in saliva

Controls: 0349 - **MassCheck**[®] Cortisol, Cortisone Saliva Control Level I
0350 - **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

73088 - 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

EC declaration valid until December 31st, 2028

Addendum Vers. 1.0

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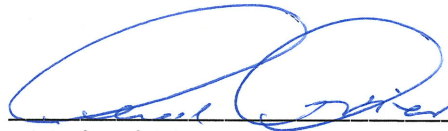
Applied harmonized standards:

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: –

Originally issued May 05th, 2022 V1.0 is still valid until December 31st, 2028
according to regulation 2024/1860.

Gräfelfing, August 05th, 2026



Michael Meier, Managing Director