

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 59017, term "Multiple steroid hormone IVD, kit, mass spectrometry"

EDMA Nomenclature term: Other Fertility Function Hormones

EMDA Nomenclature code: 12-05-01-90-00

IVDD Classification: other product

Reagent Kits: 72072/C - **MassChrom**[®] Steroids in serum/plasma
72072/96 - **MassChrom**[®] Steroids in serum/plasma
72072/480 - **MassChrom**[®] Steroids in serum/plasma

Calibrators: 72038 - 6PLUS1[®] Multilevel Serum Calibrator Set **MassChrom**[®]
Steroid Panel 1
72039 - 6PLUS1[®] Multilevel Serum Calibrator Set **MassChrom**[®]
Steroid Panel 2

Controls: 0341 - **MassCheck**[®] Steroid Panel 1 Serum Control Level I
0342 - **MassCheck**[®] Steroid Panel 1 Serum Control Level II
0343 - **MassCheck**[®] Steroid Panel 1 Serum Control Level III
0345 - **MassCheck**[®] Steroid Panel 2 Serum Control Level I
0346 - **MassCheck**[®] Steroid Panel 2 Serum Control Level II
0347 - **MassCheck**[®] Steroid Panel 2 Serum Control Level III

Products:
72011 - Mobile Phase A
72002 - Mobile Phase B
72033 - Elution Buffer
72044 - Internal Standard Mix
72005 - Extraction Buffer
72006 - Reconstitution Buffer

72077 - Equilibration Reagent 1
72008 - Equilibration Reagent 2
72009 - Rinsing Solution
72012 - Wash Buffer
72055 - Sample Clean Up Columns
72056 - Steroid Collection Plates
72057 - Steroid 96 SPE Well Plate
72059 - Piercable Adhesive Seals for 96 SPE Well Plates
72110 - Analytical Column
72058 - Waste Plate
72019 - Tuning Mix *MassChrom*[®] Steroid Panel 1
72020 - Tuning Mix *MassChrom*[®] Steroid Panel 2
72088 - System Check Solution *MassChrom*[®] Steroid Panel 1
72099 - System Check Solution *MassChrom*[®] Steroid Panel 2

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