

## 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 60484, term "Multiple vitamin IVD, kit, liquid chromatography"

EDMA Nomenclature term: Other Vitamin Tests

EDMA Nomenclature code: 12-07-02-90-00

IVDD Classification: other product

Reagent Kit: 34000 - Vitamins A and E in Serum/Plasma - HPLC  
34000/Premix - One Step Vitamins A and E in Serum/Plasma - HPLC  
34034/Premix - One Step Vitamins A and E in Serum/Plasma - HPLC  
34700/F - Automated Vitamins A and E in Serum/Plasma - HPLC  
34900/UHPLC - One Step Vitamins A and E in Serum/Plasma - UHPLC  
34900/F - Automated Vitamins A and E in Serum/Plasma - UHPLC  
34934/UHPLC - One Step Vitamins A and E in Serum/Plasma - UHPLC

Calibrator: 34004 - Serum Calibration Standard

Controls: 0032 - Serum Control Level I + II  
0036 - Serum Control Level I  
0037 - Serum Control Level II

Products:  
34001 - Mobile Phase  
34002 - Mobile Phase (10x)  
34003 - Precipitation Reagent II  
34006 - Precipitation Reagent I  
34008 - Internal Standard  
34100 - HPLC Column  
34708 - Internal Standard  
34757 - 96 Well Filter Plates  
34758 - 96 Well Collection Plates

EC declaration valid until May 26<sup>th</sup>, 2027

34760 - Pierceable Heat Seals for 96 Well Plates

34906 - Pre-mixed Reaction Tubes

34966 - Pre-mixed Solution

18034 - Precolumn Cartridge 4/10

19034 - UHPLC Precolumn Cartridge

meet all applicable requirements of the directive 98/79/EC.

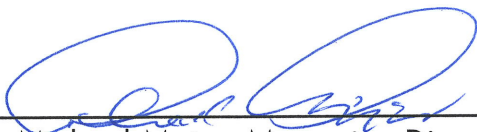
Conformity assessment procedure: Annex III of the directive 98/79/EC

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 02<sup>nd</sup>, 2022



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Michael Meier, Managing Director

