EU-Declaration of Conformity

Manufacturer	Chromsystems Instruments & Chemicals GmbH
Address	Am Haag 12 82166 Gräfelfing, Germany
SRN (single registration number)	DE-MF-000010089

Order No.	Device Description	EMDN Code
Basic UDI-DI: 4250317340004H		
34400	**HPLC Reagent Kit Vitamins A and E in serum/plasma with Reaction Vials**	W01010499
34400-DWP	**HPLC Reagent Kit Vitamins A and E in serum/plasma with 96 Deep Well Plates**	W01010499
34400-BK	**HPLC Basic Kit Vitamins A and E in serum/plasma with Reaction Vials**	W01010499
34400-DWP-BK	**HPLC Basic Kit Vitamins A and E in serum/plasma with 96 Deep Well Plates**	W01010499
0032	Serum Control Bi-Level (I+II)	W0101050299
0036	Serum Control Level I	W0101050299
0037	Serum Control Level II	W0101050299
34001	Mobile Phase	W01019099
34002	Mobile Phase	W01019099
34004	Serum Calibration Standard	W0101050302
34300	HPLC Column (equilibrated, with test chromatogram)	W01019099
34404	Internal Standard	W0101050399
34405	Precipitation Reagent	W01019099
34456	96 Deep Well Plates	W01019099
34459	Cross-slitted Adhesive Seals for 96 well plates	W01019099
34760	Pierceable Heat Seals for 96 well plates	W01019099

Device Intended Purpose	The Chromsystems reagent kit "Vitamins A and E in serum/plasma" is an in vitro diagnostic medical device for professional use in clinical laboratories for the quantitative determination of vitamin A (retinol) and vitamin E (α-tocopherol) in human serum and plasma samples. Sample preparation is carried out manually, and analytic separation is done via high performance liquid chromatography (HPLC). The kit is intended to be used for determination of vitamin A and E levels where indicated – for screening in patients with suspected vitamin A and/or E deficiency, – for screening in patients with suspected vitamin A and/or E excess, – for monitoring of patients under vitamin A and/or E supplementation.
Risk Class	B, as per EU Regulation 2017/746, Annex VIII, Rules 6

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GMDN Code	60484 "A collection of reagents and other associated materials intended to be used for the qualitative and/or quantitative detection of multiple vitamins in a clinical specimen, using a liquid chromatography method."		
Notified Body	TÜV Süd Product Service GmbH Ridlerstraße 65, 80339 Munich, Germany	Identification No.	0123
Conformity Assessment	Conformity assessment based on a quality management system and on assessment of technical documentation - Annex IX		
Declarations This EU declaration of conformity is issued under the sole responsibility of the manufacturer. The devices that are covered by the present declaration are in conformity with the In-Vitro Diagnostic Medical Devices Regulation (2017/746/EU) (IVDR).			
Following Common Specifications were considered as part of determining device conformity with the IVDR: Not applicable as no Common Specifications exist for the concerned device.			
Additional information	n/a		
This EU declaration of conformity is issued by			
Gräfelfing, October 27th, 2023 Michael Meier, Managing Director	Gräfelfing, October 27th, 2023 Dr. Ralf Fischer, PRRC		
EU declaration of conformity valid until:	July 20th, 2027	Version: 2.0	

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