

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

<p>Device Intended Purpose</p>	<p>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).</p> <p>The kit is intended to be used for determination of vitamin A and E levels where indicated</p> <ul style="list-style-type: none"> - 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
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	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9 1066 EP Amsterdam The Netherlands	Identification No.	2797
Conformity Assessment	Conformity assessment based on a quality management system and on assessment of technical documentation - Annex IX Chapters I and III		
Certificates issued	EU Quality management System Certificate (IVDR) IVDR 838647		
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, March 23 rd , 2026 Michael Meier, Managing Director		 Gräfelfing, March 23 rd , 2026 Dr. Ralf Fischer, PRRC	
EU declaration of conformity valid until:	March 22 nd , 2031	Version: 3.0	