

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: 4250317accessoryJG		
18010	Precolumn Cartridge 4/10	W01019099
15009	PEEK-encased Prefilter 5 µm	W01019099
15011	PEEK-encased Prefilter 2 µm	W01019099
15012	PEEK-encased Prefilter 0.5 µm	W01019099
15013	PEEK-encased Prefilter 2 µm	W01019099
15061	Prefilter 0.5 µm	W01019099
15071	Stainless Steel Prefilter 0.5 µm	W01019099
55018	Restrictor Capillary	W01019099

Device Intended Purpose	n/a	
Risk Class	A, as per EU Regulation 2017/746, Annex VIII, Rule 5	
GMDN Code	n/a	
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 Chapters I and III	
Certificates issued	not applicable	
Declarations	<p>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).</p>	

Following Common Specifications were considered as part of determining device conformity with the IVDR:

Not applicable as no Common Specifications exist for the concerned devices.

Additional information	n/a
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This EU declaration of conformity is issued by



Gräfelfing, November 06th, 2025
Michael Meier, Managing Director



Gräfelfing, November 06th, 2025
Dr. Ralf Fischer, PRRC

EU declaration of conformity valid until:	November 05 th , 2030	Version: 2.0
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