

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

Declarations

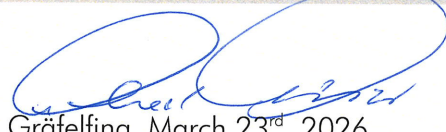
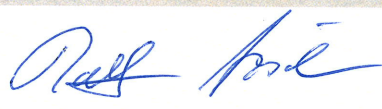
This EU declaration of conformity is issued under the sole responsibility of the manufacturer. The devices that are covered by the present declaration are in conformity with the In-Vitro Diagnostic Medical Devices Regulation (2017/746/EU) (IVDR).

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

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

Additional information	n/a
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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
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EU declaration of conformity valid until:	March 22 nd , 2031	Version: 3.0
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