

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
15091	Stainless Steel Prefilter 0.2 µm	W01019099
55018	Restrictor Capillary	W01019099

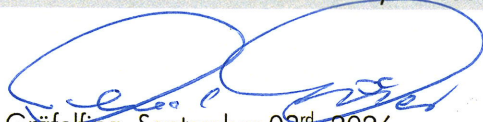
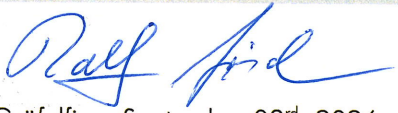
Device Intended Purpose	n/a
Risk Class	A, as per EU Regulation 2017/746, Annex VIII, Rule 5
GMDN Code	n/a

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
------------------------	-----

This EU declaration of conformity is issued by		
		
Gräfelfing, September 03 rd , 2026 Michael Meier, Managing Director	Gräfelfing, September 03 rd , 2026 Dr. Ralf Fischer, PRRC	
EU declaration of conformity valid until:	September 02 nd , 2031	Version: 4.0