

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
55015	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			
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, July 30th, 2025
Michael Meier, Managing Director



Gräfelfing, July 30th, 2025
Dr. Ralf Fischer, PRRC

EU declaration of conformity valid until:

July 29th, 2030

Version: 1.2