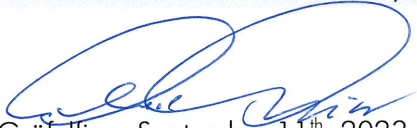



## EU-Declaration of Conformity

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
15061	Prefilter, 0.5 µm	W01019099
15071	Stainless Steel Prefilter 0.5 µm	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	n/a	Identification No. n/a
Conformity Assessment	Conformity assessment based on a quality management system and on assessment of technical documentation - Annex IX	
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:	<p>Not applicable as no Common Specifications exist for the concerned device.</p>	
Additional information	n/a	
This EU declaration of conformity is issued by		
 Gräfelfing, September 11 <sup>th</sup> , 2023 Michael Meier, Managing Director		 Gräfelfing, September 08 <sup>th</sup> , 2023 Dr. Ralf Fischer, PRRC
EU declaration of conformity valid until:	August 31 <sup>th</sup> , 2028	Version: 1.0