EU DECLARATION OF CONFORMITY

Identification of the Product	
Basic UDI-DI	9010302000200K2
Product Name	**Ultrastop pro med. Solution**
Trade Name	ULTRASTOP pro med. Lösung ULTRASTOP pro med. Solution ULTRASTOP pro med. Oplossing
Product Code (REF)	1019869
Intended purpose	Prevention of fogging of medical optics
Risk class in accordance with the rules set out in regulation (EU) 2017/745 Annex VIII	IIa according to rule 7
Manufacturer Details	
Manufacturer	MoNo chem-pharm Produkte GmbH Leystraße 129, A-1200 Vienna SRN: AT-MF-000000282
Common Specifications	
Common Specifications used	Not applicable
Conformity Assessment	
Notified Body Identification number	TÜV SÜD Product Service GmbH Ridlerstraße 65, D-80339 Munich 0123
Procedure according to regulation (EU) 2017/745	Annex IX (Quality Management System and Technical Documentation)
Number of Certificate	G10 005322 0004 Rev. 00
Quality Management System	
Applied Standard	EN ISO 13485:2016
Number of Certificate	Q5 005322 0001 Rev. 01

We declare under sole responsibility that the product described above complies with Regulation (EU) 2017/745 on Medical Devices (MDR). The product is CE marked.

Valid until: 21 March 2028 or until product change

Vienna, 22 March 2023

Dr. Bernhard Wittmann
(*Person Responsible for Regulatory Compliance*)
MoNo chem-pharm Produkte GmbH