



EU DECLARATION OF CONFORMITY

Identification of the Product	
Basic UDI-DI	9010302000100JV
Product Name	Ultrastop Antifog Agent 25 ml bottle with dropper pipette
Trade Name	ULTRASTOP ANTIBESCHLAGMITTEL 25 ml Flasche mit Tropfpipette / ULTRASTOP ANTIFOG AGENT 25 ml bottle with dropper pipette / ULTASTOP PRODUIT ANTIBUEÉ Flacon avec pipette compte-gouttes, 25 ml/ ULTRASTOP ANTICONDENS MIDDEL 25 ml flacon met druppelaar
Product Code (REF)	5031991
Intended purpose	Prevention of fogging of medical optics
Risk class in accordance with the rules set out in Regulation (EU) 2017/745 Annex VIII	I according to rule 5
Manufacturer Details	
Manufacturer	MoNo chem-pharm Produkte GmbH Leystraße 129, A-1200 Wien SRN: AT-MF-000000282
Common Specifications	
Common Specifications used	Not applicable
Conformity Assessment	
Procedure according to regulation (EU) 2017/745	Art. 52 (7) issuing the EU declaration of conformity after drawing up the technical documentation set out in Annexes II and III.
Quality management system	
Applied Standard	EN ISO 13485:2016
Number of Certificate	Q5 005322 0001

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

Valid until: 12/03/2028 or until product change

Vienna, 13.03.2023

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