CERTIFICATE

This is to certify that the company

MoNo chem-pharm Produkte GmbH

Leystraße 129
1200 Wien
Austria

with the organizational units/sites as listed in the annex

has implemented and maintains a **Quality Management System**.

Scope of certification:
Design, development, manufacture and distribution of sterile and non-sterile medical devices in liquid form for the product categories of anti-fogging agents for medical optics, solutions for ENT applications, inhalation agents and eye drops.
- AUS (a), BRA, CND, JPN, USA (a,b,c,d)

Through an audit, documented in a report, performed by DQS Medizinprodukte GmbH, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

including applicable country-specific regulatory requirements, as indicated below the scope (full references of abbreviations are listed in the annex)

Certificate registration no.	529133 MDSAP16
Certificate unique ID	1000304013
Effective date	2026-07-13
Expiry date	2029-07-12
Frankfurt am Main	2026-07-13

MDSAP
Medical Device Single Audit Program

DQS Medizinprodukte GmbH

Sven Hoffmann
Managing Director

Annex to certificate
Certificate registration No.: 529133 MDSAP16
Certificate unique ID: 1000304013
Effective date: 2026-07-13

MoNo chem-pharm Produkte GmbH

Leystraße 129
1200 Wien
Austria

Audited site	REPs FEI No.: site scope and country-specific requirements
31635222 **MoNo chem-pharm Produkte GmbH** Leystrasse 129 1200 Vienna Austria	Design, development, manufacture and distribution of sterile and non-sterile medical devices in liquid form for the product categories of anti-fogging agents for medical optics, solutions for ENT applications, inhalation agents and eye drops. **- AUS (a), BRA, CND, JPN, USA (a,b,c,d)** **REPs FEI No.: F008987**
31636891 **MoNo chem-pharm Produkte GmbH** Industriestrasse VI Haus 2 7052 Müllendorf Austria	Distribution of sterile and non-sterile medical devices in liquid form for the product categories of anti-fogging agents for medical optics, solutions for ENT applications, inhalation agents and eye drops. **- AUS (a), BRA, CND, JPN, USA (a,b,c,d)** **REPs FEI No.: F008987**
31635223 **MoNo chem-pharm Produkte GmbH** Mondpichlerplatz 1 7053 Hornstein Austria	Manufacture of sterile and non-sterile medical devices in liquid form for the product categories of anti-fogging agents for medical optics, solutions for ENT applications, inhalation agents and eye drops. **-AUS (a), BRA, CND, JPN, USA (a,b,c,d)** **REPs FEI No.: F008987**

Annex to certificate
Certificate registration No.: 529133 MDSAP16
Certificate unique ID: 1000304013
Effective date: 2026-07-13

MoNo chem-pharm Produkte GmbH

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1200 Wien
Austria

Full references of country-specific requirements of MDSAP participating Regulatory Authorities

Abbreviation	Jurisdiction	Reference
AUS	Australia	(a) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 1 – Full Quality Assurance Procedure (b) Therapeutic Goods (Medical Devices) Regulations 2002, Schedule 3, Part 4 – Production Quality Assurance Procedure
BRA	Brazil	RDC ANVISA n. 665/2022 RDC ANVISA n. 551/2021 RDC ANVISA n. 67/2009
CND	Canada	Medical Devices Regulations – Part 1- SOR 98/282 Medical Devices Regulations – Part 1.1 – SOR 98/282 (as applicable)
JPN	Japan	MHLW Ministerial Ordinance 169, Article 4 to Article 68 Japan PMD Act (as applicable)
USA	United States	(a) 21 CFR Part 803 (b) 21 CFR Part 806 (c) 21 CFR Part 807 (d) 21 CFR Part 820 (e) 21 CFR Part 821