

## CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **MedicAir Suisse SA**, **Via Laveggio 2**, **6850 Mendrisio**, Authorisation No. 512481-102656874 with its site **MedicAir Suisse SA**, **Via Laveggio 2**, **6850 Mendrisio**, **Switzerland**, Site No. 1005996 has been duly authorised to perform the manufacturing activities according to the table below;

that the company is keeping the required level for Good Manufacturing Practices for Medicinal Products (GMP) according to the Swiss regulations in force. These regulations are in accordance with the requirements for good practices in the manufacture and quality control of the Pharmaceutical Inspection Convention/Co-operation Scheme (PIC/S) as well as with The Good Manufacturing Practice requirements referred to in the Agreement of Mutual Recognition between the European Union/Canada and Switzerland;

that the manufacturing plant of the company is subject to official periodic inspections; the last regular inspection was conducted on **28.09.2021** (dd.mm.yyyy).

No.	Operation	Scope*
1	MANUFACTURE OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)	
1.2	Non-sterile products	
1.2.1 1.2.1.7 1.2.2	Non-sterile products (processing operations for the following dosage forms) Medicinal gases Batch certification (technical release)	H/V H/V
1.5	Packaging	
1.5.1 1.5.1.7	Primary packaging Medicinal gases	H/V
1.6	Quality control testing	
1.6.3	Chemical/Physical	HAV

\* Scope of authorisation:

H/V Human and veterinary medicinal products, without investigational products Veterinary medicinal products only, without investigational products

I Human investigational medicinal products

Not specified

Berne, **08.11.2021** (dd.mm.yyyy)

No. GMP-CH-1002674

Swissmedic, Swiss Agency for Therapeutic Products

Luxshana Santhirasegarar

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