

## CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Proderma AG, Nebikerstrasse 60, 6247 Schötz**, Authorisation No. 511673-102625654 with its site **Proderma AG, Nebikerstrasse 60, 6247 Schötz, Switzerland**, Site No. 1005794 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 **07.11.2018** (dd.mm.yyyy).

No.	Operation	Scope*
<b>1</b>	<b>MANUFACTURE OF MEDICINAL PRODUCTS (WITHOUT LABILE BLOOD PRODUCTS)</b>	
<b>1.5</b>	<b>Packaging</b>	
1.5.1	Primary packing	
1.5.1.5	Liquids for external use	H/V
1.5.1.8	Other solid dosage forms	H/V
1.5.1.11	Semi-solids	H/V
1.5.1.13	Tablets	H/V
1.5.2	Secondary packing	H/V
<b>1.6</b>	<b>Quality control testing</b>	
1.6.3	Chemical/Physical	H/V
Primary packaging restricted to small flexible packagings and plastic containers.		

\* Scope of authorisation:

- H/V Human and veterinary medicinal products, without investigational products
- V Veterinary medicinal products only, without investigational products
- I Human investigational medicinal products
- Not specified

Berne, 12.02.2020 (dd.mm.yyyy)  
No. GMP-CH-1000863

Swissmedic, Swiss Agency for  
Therapeutic Products



*J. Büchi*

Jacqueline Büchi