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CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Biogel AG, 6106 Werthenstein** with its site **Biogel AG, Gewerbering 6, 6105 Schachen, Switzerland**, has been duly authorized to manufacture and distribute active pharmaceutical ingredients (APIs) restricted to gelatine;

that the company is keeping the required level for good practices in the manufacture of active pharmaceutical ingredients (APIs) 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) and the Directives of the European Commission;

that the manufacturing plant of the company is subject to official periodic inspections; the last regular inspection was conducted on **January 22, 2019**;

that the requirements regarding manufacture and quality control for active pharmaceutical ingredients (APIs) for export are identical to those applicable to active pharmaceutical ingredients (APIs) sold in Switzerland.

Berne, July 18, 2019
No. 19-1005

Swissmedic, Swiss Agency for Therapeutic Products

Dr. Alfred Ryf

Swiss Agency for Therapeutic Products
swissmedic

Swissmedic | Hallerstrasse 7 | Postfach | CH-3000 Bern 9 | www.swissmedic.ch | Tel. +41 58 462 02 11 | Fax +41 58 462 02 12