

CERTIFICATE OF GMP COMPLIANCE

We certify herewith

that the company **Ferring International Center SA, Chemin de la Vergognausaz 50, 1162 St-Prex, Switzerland**, has been duly authorized to manufacture and distribute medicinal products and investigational medicinal products;

that the company is manufacturing the following dosage forms:

- solid dosage forms
- investigational medicinal products
 - including solid dosage forms

that the company is performing the following activities:

- secondary packing of medicinal products

that the finished medicinal products put on the market in Switzerland by the company are subject to appraisal and authorisation by our agency;

that the company is keeping the required level for good practices in the manufacture of medicinal products and investigational medicinal products 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;

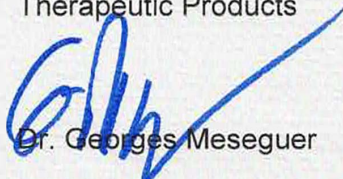
that the manufacturing plant of the company is subject to official periodic inspections; the last regular inspection was conducted on **October 15-19, 2018**;

that the requirements regarding manufacture and quality control for medicinal products and investigational medicinal products for export are identical to those applicable to medicinal products and investigational medicinal products sold in Switzerland.

Berne, August 6, 2019
No. 19-1060



Swissmedic, Swiss Agency for
Therapeutic Products



Dr. Georges Meseguer



APOSTILLE
(Convention de la Haye du 5 octobre 1961)

1. País. CONFEDERACIÓN SUIZA,

El presente documento público

2. ha sido firmado por Georges Meseguer

3. actuando en calidad de funcionario

4. se halla sellado/timbrado con Swissmedic

Instituto suizo de los productos terapéuticos

Certificado

5. en Berna

6. el 15.AUG. 2019

7. por Gaëlle Cafaro-Vullierat
funcionaria de la Cancillería de la Confederación Suiza

8. con el número.....019853

9. Sello/timbre

10. Firma

Cancillería de la Confederación Suiza



Tasa CHF 2.-