香港特別行政區政府
衞生署
醫療儀器科
網站：www.mdco.gov.hk

**Medical Device Division,**
**Department of Health,**
**Government of the Hong Kong**
**Special Administrative Region**
**Website:**www.mdco.gov.hk

# 表列證書
# CERTIFICATE OF LISTING

| | | |
|---|---|---|
| 表列號碼<br>Listing No. | : | 120153 |
| 修訂本號碼<br>Revision No. | : | c |
| 廠名、品牌及型號<br>Make, Brand Name and Model | : | European Pharma Group InsuJet needle-free injection device, Nozzle & Piston, 10ml (vial) adaptor, 3ml adaptor (for cartridge & disposable insulin pens), Comfort ring |
| 儀器名稱<br>Device Description | : | Injectors, Medication/Vaccine, Needleless |
| 製造商<br>Manufacturer | : | European Pharma Group BV<br>Beechavenue 127 Euro Off 3e, 1119 RB Schiphol - Rijk, The Netherlands |
| 製造地點<br>Manufacturing Site | : | (see Certificate Attachment No.1 for Manufacturing Site) |
| 本地負責人<br>Local Responsible Person | : | European Pharma Group Limited |

茲證明上述產品已在衞生署的「醫療儀器行政管理制度」中表列。上述本地負責人已由製造商委任，並承諾遵守「醫療儀器行政管理制度」的規定。

This is to certify that the product described above has been listed with the Department of Health under the Medical Device Administrative Control System (MDACS). The above Local Responsible Person has been designated by the Manufacturer and has undertaken to comply with the MDACS requirements.

| | | |
|---|---|---|
| 發出日期<br>Date of issue | : | 28 October 2019 |
| 有效至<br>Valid until | : | 1 June 2022 |

衞生署署長
(張勇仁醫生代行)
(Dr Terence CHEUNG)
for Director of Health

附件一 **Attachment No. 1**



| | | |
|---|---|---|
| 表列號碼<br>Listing No. | : | 120153 |
| 修訂本號碼<br>Revision No. | : | c |
| 廠名及型號<br>Make and Model | : | European Pharma Group (see below for model name(s) and product codes) |
| 製造商<br>Manufacturer | : | European Pharma Group BV |
| 製造地點<br>Manufacturing Site | : | (see Page One of Attachment No. 1) |
| 發出日期<br>Date of issue | : | 28 October 2019 |

Manufacturing Site(s):
1) European Pharma Group BV, Beechavenue 127 Euro Off 3e, 1119 RB Schiphol - Rijk, The Netherlands
2) European Pharma Group Ltd. CN, Room 508, 509, Unit 2, Building 25, Keyuan West Industrial Zone, No. 5 Kezi West Road, Nanshan, Shenzhen, China

Model name(s) and product codes:
InsuJet needle-free injection device, Nozzle & Piston, 10ml (vial) adaptor, 3ml adaptor (for cartridge & disposable insulin pens), Comfort ring

----------End of List----------

衞生署署長
(張勇仁醫生代行)
(Dr Terence CHEUNG)

衞生署
醫療儀器科

香港太古城太古灣道 14 號
6 樓 604 室

**DEPARTMENT OF HEALTH**
**MEDICAL DEVICE DIVISION**

ROOM 604, 6/F,
14 TAIKOO WAN ROAD,
TAIKOO SHING, HONG KONG

本署檔號 OUR REF.: ( 12 ) in AN002756_3

來函檔號 YOUR REF.:

電　　話 TEL.: 3107 8484

傳　　真 FAX No.: 3157 1286

28 October 2019

European Pharma Group Limited
Room 01, 23/F, On Hong Commercial Building,
145 Hennessy Road,
Wan Chai, HK
(Attn: Cathy Gao / Robin Liu)

Dear Sir / Madam,

Application No. AN002756_3
Listing under the Medical Device Administrative Control System

I refer to your above application for changes on the listing of the following device:

European Pharma Group
InsuJet needle-free injection device,
Nozzle & Piston, 10ml (vial) adaptor, 3ml adaptor (for cartridge & disposable insulin pens), Comfort ring Injectors, Medication/Vaccine, Needleless

It is my pleasure to inform you that your application has been approved./~~approved with the following conditions:~~*1*2

I enclose herewith the revised Certificate of Listing for your retention. Please observe the *Code of Practice COP-01: Code of Practice for Local Responsible Persons and Guidance Notes GN-03: Adverse Incident Reporting by Local Responsible Persons.* The latest revisions of these documents can be downloaded from our website www.mdco.gov.hk.

The approval will be valid until the expiry date of the revised Certificate provided that conditions specified above, if any, and all the listing requirements are complied with. I would like to remind you that failure to comply with any of the conditions or requirements may lead to cancellation of the listing.

Yours faithfully,

(WONG Mei-shing)
for Director of Health

/encl.

*1- delete as appropriate

*2- appeal against any conditions of approval shall be made to the Secretary to Medical Device Administration Appeal Committee within 4 weeks from the date of this letter