EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60131254 0001

Report No.: 15051546 007

Manufacturer:
Promisemed Medical Devices Inc.
170-422 Richards Street
Vancouver BC V6B 2Z4
Canada

Products:
Insulin Needles, Blood Lancets

(see attachment for additional site included)

Replaces Approval, Registration No.: DD 60122305 0001

Expiry Date: 2022-09-19

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2018-09-17

Date: 2018-09-17

Notified Body

X. Ren

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg

TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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Doc. 1/1, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60131254 0001
Report No.: 15051546 007

Manufacturer:
Promisemed Medical Devices Inc.
170-422 Richards Street
Vancouver BC V6B 2Z4
Canada

Site included:

No. 12, Longtan Road, Cangqian Street, Yuhang District,
Hangzhou City, 311121 Zhejiang, China

Notified Body

Date: 2018-09-17

X. Ren