

## CERTIFICATE

Cert No:

086-03-026-00215

Date of issue:

18/05/2018

## CE Technical Documentation Review 93/42/EEC Annex VII

Manufacturer

: InnoveMed Bio-tech Co., Ltd.

9F.-1, No.420, Sec. 1, Keelung Rd., Xinyi Dist., Taipei City 110, Taiwan

(R.O.C.)

Product(s)

: Water Based Lubricant

Model(s)

: PJ-LBW101-100B, PJ-LBM101-50B

PJ-LBW101-250B, PJ-LBW101-100B-EU PJ-LBW101-100B-E, PJ-LBS101-03B PJ-LBM101-50B-EU, PJ-LBM101-50B-E

Requirements

: Medical Devices Directive 93/42/EEC

Classification

: Class 1

(according to manufacturer's declaration)

**Examination Intent**: Examination the completeness of the Technical Documentation according to

the requirements of the Medical Devices Directive 93/42/EEC Annex VII.

Report No.

: 086-03-011-01634

Date of expiry

: 09/05/2023

SWISS APPROVAL TECHNISCHE BEWERTUNG S.A. as a Third Party Certification Body, hereby certifies that the provided Technical Documentation (No.: TCF-YN170805, Revision A/0, Date: 10/05/2018) of above mentioned products has been examined by us, and we confirm that no Noncompliance according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII was detected.

This Certificate is issued in conjunction with the above mentioned report and reflects findings during inspection in time and place only for the product and configuration described hereby and does not release buyer and/or seller from their contractual responsibilities.

All modifications to the Technical Documentation should be first submitted to our Company to ensure further validity of this attestation.

TECHNIS

(Simon Jiang)

on behalf of Company (George Paparidis)

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