



innotech

INSTITUTE OF GLOBAL CERTIFICATION



Management System Certification Body No. MSCB-105

## CERTIFICATE

No. 18-A-0959 IGC

This is to certify that the Quality Management System of

**INNOTECH Inc.**

of

16, Sarihyeon-ro, Ilsandong-gu, Goyang-si, Gyeonggi-do, Korea

Company Reg. No.: 128-87-04644

has implemented and documented a quality management system in compliance with the requirements of the standard

**ISO 9001:2015**

for

**Design & Development, Production and Sales of Manually Operated Infusion Pump**

The certificate is issued on the basis of the results mentioned in the pertinent audit report. Validity of the certificate is conditionally limited by positive results of surveillance audits, which the certified company committed to undergo.

This certificate can be invalid if the certificate holder does not fulfill the conditions set out in the certification agreement.

Initial issue date: Jul. 03, 2018

Expire date: Jul. 02, 2021



*Betty Kim*  
Betty Kim  
Head of Certification Body

Rm. 501, Daeryung techno town, 638, Seobusaet-gil, Geomcheon-gu, Seoul, Republic of Korea  
www.igicert.org



## CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM APPROVAL EC CERTIFICATE

n. 0068/QCO-DM/022-2018

according to Annex II of Directive 93/42/EEC on Medical Devices as amended

MIT hereby declares that an examination of the under mentioned Full Quality Assurance System has been carried out following the requirements of the legislation to which the undersigned is subjected, Transposing annex II (with the exemption of section 4) of the Directive 93/42/EEC on Medical Devices. MIT certifies that the Full Quality Assurance System conforms with the relevant provisions of the aforementioned legislation. The validity of this certificate is subjected to the positive result of required surveillance audits.

MANUFACTURER	INNOTECH Inc. 16, Sarihyeon-ro, Ilsandong-gu, Goyang-si, 10316 Gyeonggi-do, Korea			
DEVICES	Infusion pump			
BRAND NAME	MediLife			
MODELS	N2015AM	N2015BM	N1015AM	N1015BM
	N2015AM-E	NS015AM	NS015BM	IO020M
	IO010M	IO005M	IO050M	IO020M-E
FIRST ISSUE	26/03/2018	CURRENT ISSUE	26/03/2018	REVISION No. 00
			EXPIRATION DATE	26/03/2021

*Donato Pizzarello*

MIT International Testing Srl  
Via Moscova, 11 - 20017 BHO (MI) - ITALY  
www.mitesting.org  
ORGANISMO NOTIFICATO - NOTIFIED BODY No. 0068

Osong Health Technology Administration Complex  
187 Osongseongyeong2-ro, Osong-eup, Heungdeok-gu,  
Cheongju-si, Chungcheongbuk-do, Korea, 28159  
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연락용

No. of Certificate : 20180057698

Date : 2018/03/14

### Certificate of Free Sales

Exporting(certifying) country : Republic of Korea  
Importing(requesting) country : Vietnam

The Ministry of Food and Drug Safety, certifies that the following firm is authorized to manufacture medical devices under the Medical Device Act and the following item(s) is(are) permitted to be freely sold in domestic and overseas markets.

Manufacturer (Registered No. : 4645)

Innotech co.,Ltd

16, Sarihyeon-ro, Ilsandong-gu, Goyang-si, Gyeonggi-do, Republic of Korea

Product-License No.	Classification
14-1453	Infusion pump, manually-operated [2]

\*Attached : List of Product Classification and Model

o Do the facilities and operations conform to KMPF as recommended by the Ministry of Food and Drug Safety?

Yes  No

*Shin Joonsu*

Director of Medical Devices Policy Division  
Department of Ministry of Food and Drug Safety

This medical device is approved by The Medical device Information & Technology Assistance Center(MDITAC) established under Article 42 of Medical Device Act.

### 특허증 CERTIFICATE OF PATENT

특허 제 10-1535947 호  
Patent Number

출원번호 제 10-2015-0021707 호  
Application Number

출원일 2015년 02월 12일  
Filing Date

등록일 2015년 07월 06일  
Registration Date

발명의 명칭 Title of the Invention  
약재 주입장치

특허권자 Patentee  
(주)이노텍(285011-0\*\*\*\*\*)  
경기도 고양시 일산동구 사리원로 16 (식사동)

발명자 Inventor  
등록사항관에 기재

위의 발명은 「특허법」에 따라 특허등록원부에 등록되었음을 증명합니다.  
This is to certify that, in accordance with the Patent Act, a patent for the invention has been registered at the Korean Intellectual Property Office.



2015년 07월 06일

특허청장  
COMMISSIONER  
KOREAN INTELLECTUAL PROPERTY OFFICE

최동규