



## EC Declaration of Conformity

*We,*

**Advanced Medical Design Co., Ltd.**  
**4~5F, No. 29, Wuquan 5th Rd., Wugu Dist., New Taipei city, 24888, Taiwan**  
**(R.O.C.)**

*In accordance with the following directive*

**Council Directive 93/42/EEC Annex II excl. section 4 as amended by all subsequent directives**  
**including Directive 2007/47/EC**

*hereby declare that:*

**Equipment: Insufflation Filter with Tubing Set**

*Model Number:*

**AIF-3000, AIF-3100, AIF-3200, AIF-3300, AIF-3400, AIF-3500**  
**and AIF-XXXX**

*is in conformity with the applicable requirements of the following documents*

<i>Ref. No.</i>	<i>Title</i>	<i>Edition date</i>
EN ISO 14971	Medical devices - Application of risk management to medical devices	2012
EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes	2012
EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2009
EN ISO 11607	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	2009
EN 980	Symbols for use in the labelling of medical devices	2008
EN ISO 11135-1	Sterilization of health care products - Ethylene oxide - Part 1: Requirements for development, validation and routine control of a sterilization process for medical devices	2007
MEDDEV. 2.7/1 Rev. 4	CLINICAL EVALUATION: A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES UNDER DIRECTIVES 93/42/EEC and 90/385/EEC	2016
MEDDEV 2.12/1 Rev. 8	GUIDELINES ON A MEDICAL DEVICES VIGILANCE SYSTEM	2013
MEDDEV 2.12/2 Rev. 2	POST MARKET CLINICAL FOLLOW-UP STUDIES A GUIDE FOR MANUFACTURERS AND NOTIFIED BODIES	2012

*I hereby declare that the equipment named above has been designed to comply with the relevant sections of the above referenced specifications. The unit complies with all applicable Essential Requirements of the Directives.*

*European Representative:*

**Lotus Global Co. Ltd.**

*1F Seasons Terrace, West Drayton, Middlesex, London, UB7 9GG, UK*

*TEL: +44 20 75868010, FAX: +44 20 79006187, Mob: 44-7888 00 3330*

*Contact Person: Peter, E-mail: lotus889@126.com, sfm88@126.com*

**Directive Classification: Class IIa by Rule 2 of MEDDEV 2.4/1 Rev. 9 (2010)**

**Date of issue: 2017.03.01**

**Place of issue: New Taipei City, Taiwan**

A handwritten signature in black ink, appearing to read 'Arnold Yeh', with the date '3/1, 2017' written to its right. The signature is positioned above a horizontal line.

**Arnold Yeh, President**

**(authorized signature)**



GLOBAL SOLUTIONS FOR MEDICAL INDUSTRY

康健生醫科技股份有限公司

台灣新北市五股區新北產業園區五權五路29號4~5樓

**ADVANCED MEDICAL DESIGN CO., LTD.**

4~5F, No.29, Wuquan 5th Rd., Wugu Dist., New Taipei City 248, Taiwan (R.O.C.)

TEL: 886-2-2290-2627 Fax: 886-2-2298-8501 [www.amdintl.com.tw](http://www.amdintl.com.tw)

Effective Date: November 02, 2017

**Advanced Medical Design Co., Ltd.**

4F~5F, No. 29, Wuquan 5th Rd.,

Wugu District, New Taipei City, 248 Taiwan R.O.C.

## Declaration

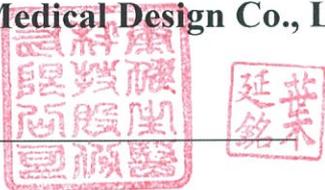
It is hereby declared the relationship of Insufflation Filter with Tubing Set's model number between Advanced Medical Design Co., Ltd. and Fannin Ltd.

The following table demonstrates the relationship of Insufflation Filter with Tubing Set's model number between Advanced Medical Design Co., Ltd. and Fannin Ltd.

Company Name	Advanced Medical Design Co., Ltd.	Fannin Ltd.
Product Name	Insufflation Filter with Tubing Set	Insufflation Filter with Tubing Set
Model Number	AIF-400Z	IFT0001
	AIF-460Z	IFT0002
	AIF-430Z	IFT0015

**Advanced Medical Design Co., Ltd.**

Signature: \_\_\_\_\_



Name: Arnold Yeh

Title: President

Date: 2017.11.02