Advanced Medical Design CO., LTD.
4F~5F, No29, Wuquan 5th Rd., Wugu Dist ., New Taipei city, 248 Taiwan
TEL: 886-2-22902627 FAX: 886-2-22988501

# 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, to be certified by NB: DNV Product Assurance AS, with CE2460**

*hereby declare that:*

*Equipment:* **Insufflation Filter with Tubing Set**

*Model Number:*

**AIF-400Z, AIF-430Z, AIF-460Z,**
**AIF-500Z, AIF-530Z, AIF-540Z, AIF-560Z,**
**AIF-600Z, AIF-630Z, AIF-640Z, AIF-660Z, AIF-670Z,**
**AIF-4300, AIF-4600, AIF-4700**

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

| *Ref. No.* | *Title* | *Edition date* |
|---|---|---|
| **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** | **2016** |
| **EN ISO 10993-1** | **Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process** | **2009** |
| **EN ISO 11607-1** | **Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems** | **2009** |
| **EN ISO 15223-1** | **Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements** | **2016** |
| **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** |

*We, Advanced Medical Design Co., Ltd. hereby declare a statement that the EU declaration of conformity is issued under the exclusive responsible for the compliance of declaration. 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.*

*Notified Body:*

**DNV Product Assurance AS**

*Veritasveien 3, 1363 Høvik, Norway*

*TEL: +47 67578800*

*Email: info@presafe.com*

*Notified Body number: 2460*

*European Representative:*

**OBELIS S.A**

*Bd. Général Wahis, 53, 1030 Brussels, Belgium*

*TEL: +3227325954*

*FAX: +3227326003*

*E-mail: mail@obelis.net*

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

*Date of issue:* **2021.08.03**

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

**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**

Effective Date: Dec. 24, 2021

**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 that if there is not any applicable regulation is changed for the Insufflation Filter with Tubing Set, the effective period of this DoC will be followed the expiration date of AMD's CE IIa license (Certificate No.10173-2017-CE-RGC-NA-PS Rev. 1.0, valid until 9 March 2023, Attachment 1).
The following table demonstrates the relationship of Insufflation Filter with Tubing Set's model number between Advanced Medical Design Co., Ltd. and MEDLINE.

| Company Name | Advanced Medical Design Co., Ltd. | MEDLINE |
|---|---|---|
| Ref. Number | AIF-660Z-81264 | ORIS-ISO |
| | AIF-660Z-81282 | ORIS15 |
| | AIF-630Z-81264 | ORISPUSH |
| | AIF-600Z-81264 | ORISLL |

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

Signature: _____

Name: Arnold Yeh

Title: General Manager

Date: 2021.12.24