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

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:

Please refer to Annex 1

is in conformity with the applicable requirements of the following documents

Ref. No.	*Title*	*Edition date*
BS EN ISO 14971	Medical devices - Application of risk management to medical devices	2019/ A.11: 2021
PD CEN ISO/TR 24971	Medical devices – Guidance on the application of ISO 14971	2020
BS EN ISO 13485	Medical devices - Quality management systems - Requirements for regulatory purposes	2016/ A.11: 2021
BS EN ISO 10993-1	Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process	2020
BS EN ISO 10993-7	Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals	2008/ A1: 2022
BS EN ISO 11607-1	Packaging for terminally sterilized medical devices - Part 1: Requirements for materials, sterile barrier systems and packaging systems	2020
BS EN ISO 11607-2	Packaging for terminally sterilized medical devices - Part 2: Validation requirements for forming, sealing and assembly processes	2020
BS EN ISO 15223-1	Medical devices - Symbols to be used with medical device labels, labelling and information to be supplied - Part 1: General requirements	2021
BS EN ISO 11135	Sterilization of health-care products - Ethylene oxide - Requirements for the development, validation and routine control of a sterilization process for medical devices	2014/ A1: 2019
BS EN ISO 11737-1	Sterilization of health care products - Microbiological methods - Part 1: Determination of a population of microorganisms on products	2018/ A1: 2021
BS EN ISO 11737-2	Sterilization of health care products - Microbiological methods - Part 2: Tests of	2020

	sterility performed in the definition, validation and maintenance of a sterilization process	
BS EN ISO 14644-1	**Cleanrooms and associated controlled environments - Part 1: Classification of air cleanliness by particle concentration**	**2015**
BS EN 62366-1	**Medical devices - Part 1: Application of usability engineering to medical devices**	**2015/ A1: 2020**
ISO/TR 20416	**Medical devices - Post-market surveillance for manufacturers**	**2020**

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 1, 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: **2022.11.23**

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

Arnold Yeh, General Manager

(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: May 06, 2025

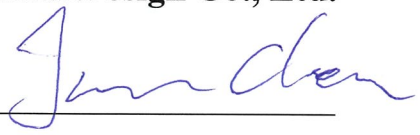
Advanced Medical Design Co., Ltd.
4F~5F, No. 29, Wuquan 5th Rd.,
Wugu District, New Taipei City, 248 Taiwan

Declaration

It is hereby declared that if there is not any applicable regulation is changed for "Insufflation Filter with Tubing Set", the effective period of this DoC will be followed the expiration date of "NB Confirmation Letter" (Expiration Date: 2028.12.31 / Reference: C657578, 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-ISOA
	AIF-660Z-81282	ORIS15A
	AIF-630Z-81264	ORISPUSHA
	AIF-600Z-81264	ORISLLA

Advanced Medical Design Co., Ltd.

Signature: 

Name: Jason Chen

Title: PRRC

Date: 2025 05 06

Notified Body Confirmation Letter Reference: C657578

To whom it may concern,

Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Advanced Medical Design Co., Ltd.

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

New Taipei City, 24888,

Taiwan

SRN Number: TW-MF-000019772

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

Place and date:
Høvik, 2023/12/19

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

André Fernandes
Management Representative

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips, and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function.
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Insufflation Filter with Tubing Set / 471160599AIF0143	IIa	N/A	Certificate number: 10173-2017-CE-RGC-NA-PS Rev. 1.0 NB number NB 2460
Suction Irrigation Set / 471160599ASI016Q	IIa	N/A	Certificate number: 10173-2017-CE-RGC-NA-PS Rev. 1.0 NB number NB 2460
Veress Needle / 471160599AVN0186	IIa	N/A	Certificate number: 10173-2017-CE-RGC-NA-PS Rev. 1.0 NB number NB 2460
Anti-Fog Solution / 471160599AAF012B	IIa	N/A	Certificate number: 10173-2017-CE-RGC-NA-PS Rev. 1.0 NB number NB 2460

Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:

Device name and Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/12/19	C657578	Initial issue

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607.
- Significant changes to design or intended purpose of the devices.
- Changes in the quality system affecting production.
- Periodical audits not held within the timeframe.