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:* **Veress Needle**

*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 10993-5** | **Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity** | **2009** |
| **EN ISO 10993-7** | **Biological evaluation of medical devices - Part 7: Ethylene oxide sterilization residuals** | **2008** |
| **ISO 10993-10** | **Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization** | **2021** |
| **BS EN ISO 10993-11** | **Biological evaluation of medical devices - Part 11: Tests for systemic toxicity** | **2018** |
| **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** | **2014/** |

| | | |
|---|---|---|
| | **development, validation and routine control of a sterilization process for medical devices** | **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 sterility performed in the definition, validation and maintenance of a sterilization process** | **2020** |
| **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 6 of MEDDEV 2.4/1 Rev. 9 (2010)**

*Date of issue:* **2022.09.26**

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

**Arnold YEH, General Manager**

**(Authorized Signature)**

GLOBAL SOLUTIONS FOR MEDICAL INDUSTRY

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**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, 24888, Taiwan

# Declaration

It is hereby declared that if there is not any applicable regulation is changed for "Veress Needle", 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 Veress Needle's model number between Advanced Medical Design Co., Ltd. and MEDLINE.

| **Company Name** | **Advanced Medical Design Co., Ltd.** | **MEDLINE** |
|---|---|---|
| **Model Number** | AVN-T120 | ORVN120A |
| | AVN-T150 | ORVN150A |

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

Signature: Jason Chen

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.