MANAGEMENT SYSTEM CERTIFICATE

Certificate no.:	Initial certification date:	Valid:
246303-2017-AQ-RGC-NA-PS	30 July 2010	31 January 2025 – 30 January 2028

This is to certify that the management system of

Advanced Medical Design Co., Ltd.

4F.~5F., No. 29., Wuquan 5th Rd., Wugu Dist., New Taipei City 24888, Taiwan

and the sites as mentioned in the appendix accompanying this certificate

has been found to conform to the Quality Management System standard:

ISO 13485:2016 / EN ISO 13485:2016

This certificate is valid for the following scope:

Design, Manufacture, Sales and Distribution of the following sterile medical device: Surgical Skin Marker, Camera Sleeves and Cover, Trocar with Cannula, Veress Needle, Smoker Filter with Tubing Set, Lap Bag, Anti-Fog Solution, Monopolar & Bipolar Connecting Cable, Sharp Box, Discard Pad, Diathermy Instrument Pouch, Light Handle Cover, Insufflation Filter with Tubing Set, Suction Irrigation Set, Disposable Laparoscopy Monopolar Instrument Access, Disposable Laparoscopy Bipolar Instrument Access

Design, Manufacture, Sales and Distribution of the following non-sterile medical device: Magnetic Instrument Mat, Sharp Box, Camera Sleeves and Cover

Contract Manufacture of Holster, Scope Cleaner, Suture Passer, AED Pad, Lap Scope Warmer Set, Morcellator

Place and date:
Høvik, 31 January 2025

NORWEGIAN ACCREDITATION
MSYS 018

For the issuing office:
DNV Product Assurance AS
Veritasveien 1, 1363 Høvik, Norway

Cecilie Gudesen Torp

Cecilie Gudesen Torp
Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid.

Certificate no.: 246303-2017-AQ-RGC-NA-PS
Place and date: Høvik, 31 January 2025

Appendix to Certificate

Advanced Medical Design Co., Ltd.

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
Advanced Medical Design Co., Ltd.	4F.~5F., No. 29., Wuquan 5th Rd., Wugu Dist., New Taipei City 24888, Taiwan	Manufacture and Distribution of the following sterile medical device: Surgical Skin Marker, Camera Sleeves and Cover, Trocar with Cannula, Veress Needle, Smoker Filter with Tubing Set, Lap Bag, Anti-Fog Solution, Monopolar & Bipolar Connecting Cable, Sharp Box, Discard Pad, Diathermy Instrument Pouch, Light Handle Cover, Insufflation Filter with Tubing Set, Suction Irrigation Set, Disposable Laparoscopy Monopolar Instrument Access, Disposable Laparoscopy Bipolar Instrument Access Manufacture and Distribution of the following non-sterile medical device: Magnetic Instrument Mat, Sharp Box, Camera Sleeves and Cover Contract Manufacture of Holster, Scope Cleaner, Suture Passer, AED Pad, Lap Scope Warmer Set, Morcellator
Advanced Medical Design Co., Ltd.	5F., No.3, Wugong 5th Rd., Xinzhuang Dist., New Taipei City 24890, Taiwan	Design and Sales of the following sterile medical device: Surgical Skin Marker, Camera Sleeves and Cover, Trocar with Cannula, Veress Needle, Smoker Filter with Tubing Set, Lap Bag, Anti-Fog Solution, Monopolar & Bipolar Connecting Cable, Sharp Box, Discard Pad, Diathermy Instrument Pouch, Light Handle Cover, Insufflation Filter with Tubing Set, Suction Irrigation Set, Disposable Laparoscopy Monopolar Instrument Access, Disposable Laparoscopy Bipolar Instrument Access Design and Sales of the following non-sterile medical device: Magnetic Instrument Mat, Sharp Box, Camera Sleeves and Cover