

MANAGEMENT SYSTEM CERTIFICATE

Certificate no.: 217318-2017-AQ-RGC-NA-PS Rev. 2.0 Initial certification date: 17 August 2006 Valid: 18 August 2021 – 17 August 2024

This is to certify that the management system of

Yaan Device Co., Ltd.

9th Fl., No. 80, Fu Hsing N. Rd., Taipei City, 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/ NS-EN ISO 13485:2016

This certificate is valid for the following scope: Manufacturing, Sales and Distribution of Copolymer Examination Gloves (Sterile & Non-Sterile).

Place and date: Høvik, 16 August 2021





For the issuing office: DNV Product Assurance AS Veritasveien 3, 1363 Høvik, Norway

Ceutie Gudesen lop

Cecilie Gudesen Torp Management Representative

Lack of fulfilment of conditions as set out in the Certification Agreement may render this Certificate invalid. ACCREDITED UNIT: DNV Product Assurance AS, Veritasveien 3, 1363 Hovik, Norway, Tel +47 67 57 88 00, www.dnv.com ICP-4-5-i5-ISO13485-f1 rev.0



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Appendix to Certificate

Locations included in the certification are as follows:

Site Name	Site Address	Site Scope
Yaan Device Co., Ltd. (HQ)	9th Fl., No. 80, Fu Hsing N. Rd., Taipei City, Taiwan.	Sales
Yaan Device Co., Ltd. (Factory)	No. 9, Jan Bin East 2 Rd., Jan-Bin Industrial Park, Sian-Si Hsiang, Chuanghua Hsien, Taiwan.	Manufacture, Purchase, QA, HR, Warehouse



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