



宏達實業股份有限公司  
YAAN DEVICE CO., LTD.

DECLARATION OF CONFORMITY  
TO CONCIL DIRECTIVE 93/42/EEC CONCERNING  
MEDICAL DEVICES



MANUFACTURER: YAAN DEVICE CO., LTD

9 F. No. 80 Fu Hsing North Road, Taipei, Taiwan  
Tel: 886-2-27527483/ Fax: 886-2-27513693

MEDICAL DEVICE : COPOLYMER STERILE EXAMINATION GLOVES  
CLASSIFICATION - ANNEX IX : CLASS I STERILE, RULE I  
CONFORMITY ASSESSMENT ROUTE: ANNEX V

WE, YAAN DEVICE CO., LTD, HEREWITH DECLARE THAT THE STATED MEDICAL DEVICES MEET THE TRANSPORTATION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC OF 14 JUNE 1993 CONCERNING MEDICAL DEVICES; INCLUDING AT 21 MARCH 2010, THE AMENDMENTS BY COUNCIL DIRECTIVE 2001/47/EEC. ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER.

STANDARDS APPLIED: EN ISO 10993-1:2018, EN ISO 10993-5:2009, EN ISO11137-1:2015  
EN ISO11137-2:2015, EN ISO 11607-1:2019, EN ISO13485:2016  
EN 455-1:2020 , EN 62366:2015 , EN 15223-1 2016  
ISO 10993-10:2018 , EN 455-4:2009

NOTIFY BODY : DNV Product Assurance AS

IDENTIFICATION NUMBER :  2460

(EC) CERTIFICATE : 10146-2017-CE-RGC-NA-PS Rev 1.0



EUROPEAN REPRESENTATIVE : AEON ASTRON EUROPE B.V.

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START OF CE-MARKING: DATE OF FIRST CE MARKING 2017- JUL- 10

PLACE, DATE OF DECLARATION: TAIPEI, TAIWAN 2021- JUL- 18

YAAN DEVICE Co., Ltd

Julie Hsieh / Sales Manager