



認可項目

Scope of accreditation

■ Info.

Organization :	Eurofins E&E Taiwan Co., Ltd.
Organization Address :	18F., No. 716, Zhongzheng Rd., Zhonghe Dist., New Taipei City 235, Taiwan (R.O.C.)
Name of Lab :	Eurofins E&E Taiwan Co., Ltd.
Add. of Lab :	18F., No. 716, Zhongzheng Rd., Zhonghe Dist., New Taipei City 235, Taiwan (R.O.C.)
Accreditation Number :	3748
Accreditation Criteria :	ISO/IEC 17025:2017 ;CNS 17025:2018
Originally Accredited :	2020/10/15
Effective Period :	2020/10/15 ~ 2023/10/14
Accredited Scope :	Testing Field
Specific Accreditation Program :	

Laboratory Head :	Koen Ke
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15 03 Medical Devices

Surgical, cosmetic, therapeutic and diagnostic laser equipment
 E 001 Safety
 IEC 60601-2-22
 EN 60601-2-22
 CAN/CSA-C22.2 NO.60601-2-22
 AS IEC 60601.2.22
 1 φ, 250 Vac max., 25 A , max., 50 Hz/60 Hz
 cl.201.8.10.4.101 Footswitch test only
 Approval Signatory:Neil Wang; Koen Ke

Endoscopic equipment
 E 001 Safety
 IEC 60601-2-18
 EN 60601-2-18
 CAN/CSA-C22.2 NO.60601-2-18
 JIS T0601-2-18
 AS/NZS IEC 60601.2.18
 1 φ, 250 Vac max., 25 A , max., 50 Hz/60 Hz
 Approval Signatory:Neil Wang; Koen Ke

Electrocardiographic monitoring equipment
 E 001 Safety
 IEC 60601-2-27
 EN 60601-2-27
 ANSI/AAMI 60601-2-27
 CAN/CSA-C22.2 No 60601-2-27
 AS/NZS IEC 60601.2.27
 1 φ, 250 Vac max., 25 A , max., 50 Hz/60 Hz
 Approval Signatory:Neil Wang; Koen Ke

Electrocardiographs
 E 001 Safety
 IEC 60601-2-25
 EN 60601-2-25
 ANSI/AAMI 60601-2-25
 CAN/CSA-C22.2 No 60601-2-25
 JIS T 0601-2-25
 AS/NZS IEC 60601.2.25
 1 φ, 250 Vac max., 25 A , max., 50 Hz/60 Hz
 Approval Signatory:Neil Wang; Koen Ke

Operating tables
 E 001 Safety
 IEC 60601-2-46

EN 60601-2-46
CAN/CSA-C22.2 No.60601-2-46
1 ϕ , 250 Vac max., 25 A , max., 50 Hz/60 Hz
Approval Signatory:Neil Wang; Koen Ke

Surgical luminaires and luminaires for diagnosis
E 001 Safety
IEC 60601-2-41
EN 60601-2-41
CAN/CSA-C22.2 No 60601-2-41
1 ϕ , 250 Vac max., 25 A , max., 50 Hz/60 Hz
exclude cl.201.10.7 Ultraviolet radiation test \ cl.201.12.1.102.2 Spectral characteristics test \ cl.201.12.1.102.3 Temperature rise in the lighted surface test \ cl.201.12.1.102.4 a) Stability of the light source test
Approval Signatory:Neil Wang; Koen Ke

Automated non-invasive sphygmomanometers
E 001 Safety
IEC 80601-2-30
EN 80601-2-30
ANSI/AAMI/IEC 80601-2-30
CAN/CSA-C22.2 No 80601-2-30
1 ϕ , 250 Vac max., 25 A , max., 50 Hz/60 Hz
Approval Signatory:Neil Wang; Koen Ke

Pulse oximeter equipment
E 001 Safety
ISO 80601-2-61
CAN/CSA-C22.2 No 80601-2-61
JIS T 80601-2-61
1 ϕ , 250 Vac max., 25 A , max., 50 Hz/60 Hz
Approval Signatory:Neil Wang; Koen Ke

Blood-glucose monitoring systems for self-testing in managing diabetes mellitus
E 001 Safety
ISO 15197
CAN/CSA-ISO 15197
1 ϕ , 250 Vac max., 25 A , max., 50 Hz/60 Hz
exclude cl.6 Analytical performance evaluation \ cl.8 User performance evaluation
Approval Signatory:Neil Wang; Koen Ke

Non-laser light source equipment intended for therapeutic, diagnostic, monitoring and cosmetic/aesthetic use
E 001 Safety
IEC 60601-2-57
EC 60601-2-57
AS IEC 60601.2.57
1 ϕ , 250 Vac max., 25 A , max., 50 Hz/60 Hz
cl.201.8.10.4.101 Footswitch test only
Approval Signatory:Neil Wang; Koen Ke

Ambulatory electrocardiographic systems
E 001 Safety
IEC 60601-2-47
EN 60601-2-47
ANSI/AAMI 60601-2-47
CAN/CSA-C22.2 No 60601-2-47
ANSI/AAMI EC57
1 ϕ , 250 Vac max., 25 A , max., 50 Hz/60 Hz
Approval Signatory:Neil Wang; Koen Ke

Medical electrical equipment and medical electrical systems used in the home healthcare environment
E 001 Safety
IEC 60601-1-11
EN 60601-1-11
ANSI/AAMI HA60601-1-11
CAN/CSA-C22.2 No 60601-1-11
1 ϕ , 250 Vac max., 25 A , max., 50 Hz/60 Hz
Approval Signatory:Neil Wang; Koen Ke

Transcutaneous electrical nerve stimulators
E 001 Safety

AAMI NS4

1 ϕ , 250 Vac max., 25 A , max., 50 Hz/60 Hz

Approval Signatory:Neil Wang; Koen Ke

Transcutaneous Electrical Nerve Stimulators (TENS)

E 001 Safety

IEC 60601-2-10

EN 60601-2-10

CAN/CSA-C22.2 No 60601-2-10

1 ϕ , 250 Vac max., 25 A , max., 50 Hz/60 Hz

Approval Signatory:Neil Wang; Koen Ke

Medical electrical equipment and medical electrical systems intended for use in the emergency medical services environment

E 001 Safety

IEC 60601-1-12

EN 60601-1-12

ANSI/AAMI/IEC 60601-1-12

CAN/CSA-C22.2 No. 60601-1-12

1 ϕ , 250 Vac max., 25 A , max., 50 Hz/60 Hz

exclude cl.10.1.4 Requirement for mechanical strength for ME EQUIPMENT intended for airborne use

Approval Signatory:Neil Wang; Koen Ke

Medical beds

E 001 Safety

IEC 60601-2-52

EN 60601-2-52

CAN/CSA-C22.2 No.60601-2-52

1 ϕ , 250 Vac max., 25 A , max., 50 Hz/60 Hz

exclude cl.201.9.8.3.3 Dynamic testing of the height adjustment mechanism

Approval Signatory:Neil Wang; Koen Ke

High frequency surgical equipment and high frequency surgical accessories

E 001 Safety

IEC 60601-2-2

EN 60601-2-2

ANSI/AAMI 60601-2-2

CAN/CSA-C22.2 NO.60601-2-2

JIS T 0601-2-2

AS/NZS 60601.2.2

1 ϕ , 250 Vac max., 25 A , max., 50 Hz/60 Hz

cl.201.8.8.3.102 Active Accessories HF leakage \ cl.201.8.8.3.103 Active Accessories HF dielectric strength \ cl.201.

8.8.3.104 Active Accessories mains frequency dielectric strength \ cl.201.8.10.4 cord-connected HAND-HELD part

s and cord-connected foot-operated control devices \ cl.201.11.1.1 Maximum temperature during Normal Use \ cl.2

01.11.1.2.1 Applied parts intended to supply heat to a Patient \ cl.201.11.6.3 Spillage on ME EQUIPMENT and ME S

YSTEMS \ cl.201.11.6.5 Ingress of water or particulate matter into ME EQUIPMENT and ME systems \ cl.201.15.4.1.

101 Compatibility with third party ACTIVE ELECTRODES \ cl.201.15.4.1.102 Retention of detachable ACTIVE ELECT

RODES only

Approval Signatory:Neil Wang; Koen Ke

Medical electrical equipment

E 001 Safety

IEC 60601-1

EN 60601-1

AS/NZS IEC 60601.1

ANSI/AAMI ES60601-1

CAN/CSA-C22.2 NO.60601-1

JIS T 0601-1

1 ϕ , 250 Vac max., 25 A , max., 50 Hz/60 Hz

exclude cl.11.4 ME equipment and ME systems intended for use with flammable anaesthetic mixtures \ Annex G Protection against hazards of ignition of flammable anaesthetic mixtures

Approval Signatory:Neil Wang; Koen Ke; Larry Lai

Medical electrical equipment – Usability

E 023 Safety

IEC 60601-1-6

EN 60601-1-6

CAN/CSA-C22.2 No 60601-1-6

IEC 62366

EN 62366

IEC 62366-1

EN 62366-1

CAN/CSA-IEC 62366-1

1 ϕ , 250 Vac max., 25 A , max., 50 Hz/60 Hz

Approval Signatory:Neil Wang; Koen Ke

Medical device software – Software life cycle processes

E 023 Safety

IEC 62304

EN 62304

1 ϕ , 250 Vac max., 25 A , max., 50 Hz/60 Hz

Approval Signatory:Koen Ke

17 04 Metrical Instrument

Laboratory equipment for the heating of materials

E 001 Safety

IEC 61010-2-010

EN 61010-2-010

UL 61010-2-010

CSA C22.2 No. 61010.2.010

1 ϕ , 250 Vac max., 25 A , max., 50 Hz/60 Hz

Approval Signatory:Neil Wang; Koen Ke

Automatic and semi-automatic laboratory equipment for analysis and other purposes

E 001 Safety

IEC 61010-2-081

EN 61010-2-081

UL 61010-2-081

CSA C22.2 No. 61010-2-081

1 ϕ , 250 Vac max., 25 A , max., 50 Hz/60 Hz

Approval Signatory:Neil Wang; Koen Ke

Laboratory equipment for mixing and stirring

E 001 Safety

IEC 61010-2-051

EN 61010-2-051

UL 61010-2-051

CSA C22.2 No. 61010.2.051

1 ϕ , 250 Vac max., 25 A , max., 50 Hz/60 Hz

Approval Signatory:Neil Wang; Koen Ke

Electrical equipment for measurement, control, and laboratory use

E 001 Safety

IEC 61010-1

EN 61010-1

CAN/CSA-C22.2 NO.61010-1

UL 61010-1

1 ϕ , 250 Vac max., 25 A , max., 50 Hz/60 Hz

Approval Signatory:Neil Wang; Koen Ke

In vitro diagnostic (IVD) medical equipment

E 001 Safety

IEC 61010-2-101

EN 61010-2-101

UL 61010-2-101

CSA C22.2 No. 61010-2-101

1 ϕ , 250 Vac max., 25 A , max., 50 Hz/60 Hz

Approval Signatory:Neil Wang; Koen Ke