MEDTECS INTERNATIONAL CORPORATION LIMITED

Medtecs Personal Protective Equipment (PPE)

Medtecs (Cambodia)

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Kampong Cham Factory
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Medtecs (Singapore)

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Medtecs (Taiwan)

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Address
11F., No.9, Songgao Rd., Xinyi Dist., Taipei City 110, Taiwan

Medtecs (Philippines)

Makati Office
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+632-817-9000

Bataan Factory
7th street Phase II, FAB, Mariveles, Bataan 2106, Philippines

PPE ITEMS

- ✓ AAMI Level 1 SMMS 22gsm Isolation Gowns P.3
- ✓ AAMI Level 2 SMMS 25gsm Isolation Gowns P.4
- ✓ AAMI Level 1 & Level 2 PP+PE 27gsm Isolation Gowns P.5
- ✓ AAMI Level 3 & Level 4 PP+PE 36gsm Isolation Gowns P.6
- ✓ AAMI Level 3 & Level 4 PP+PE 63gsm Isolation Gowns P.7
- ✓ Chemo Gown P.8
- ✓ AAMI Level 3 SMS 50gsm Surgical Gowns P.9
- ✓ AAMI Level 4 SFT 66gsm Surgical Gowns P.10
- ✓ Disposable Open Back PE Gowns P.11
- ✓ Reusable Isolation Gown P.12
- ✓ Protective Coverall with Hood P.13
- ✓ Protective Coverall with Hood & Tape P.14
- ✓ Dust Proof Clothing / Flight Suit P.15
- ✓ ASTM Level 1 / Type IIR 3-Ply Face Mask P.16
- ✓ KN95 Masks P.17
- ✓ 3 Ply Reusable Protective Mask P.18
- ✓ Safety Goggles P.25
- ✓ Face Shields P.26
- ✓ Disposable Bouffant Caps P.27
- ✓ Disposable Shoe Covers P.28

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

AAMI Level 1 PP+PE 27gsm Isolation Gowns

- ✓ PP+PE coating materials
- ✓ AATCC42 water impact test < 4.5g
- ✓ Over-the-head and tie at the waist for secure protection
- ✓ Stich sewing seam
- ✓ Thumb-up type
- ✓ AAMI Level 1 protection (AAMI - Association for the Advancement of Medical Instrumentation)

- Material: 100% PP+PE Coating
- Fabric weight: 27gsm
- Style: IL-1027WTUS
- Color: White
- Size: Free size
- Packing: 10pcs/bag, 100pcs/carton (52*28*33cm)
- G.W.: 8.2 KGS

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

AAMI Level 1 SMMS 22gsm Isolation Gowns

- ✓ Four-layer, fluid-resistant and breathable SMMS materials
- ✓ AATCC42 water impact test < 4.5g
- ✓ Over-the-head and tie at the waist for secure protection
- ✓ Stich sewing seam
- ✓ Thumb-up type
- ✓ AAMI Level 1 protection (AAMI - Association for the Advancement of Medical Instrumentation)

- Material: 100% PP SMMS
- Fabric weight: 22gsm
- Style: IL-2022YTUU
- Color: Yellow
- Size: Free size
- Packing: 10pcs/bag, 100pcs/carton (52*28*33 cm)
- G.W.: 6.7 KGS

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

AAMI Level 2 SMMS 25gsm Isolation Gowns

- ✓ Four-layer, fluid-resistant and breathable SMMS materials
- ✓ AATCC127 Hydrostatic pressure test reaches ≥ 20cm
- ✓ AATCC42 water impact test < 1.0g
- ✓ Over-the-head and tie at the waist for secure protection
- ✓ Ultra-sonic welded seam
- ✓ Thumb-up type
- ✓ AAMI Level 2 protection (AAMI - Association for the Advancement of Medical Instrumentation)

- Material: 100% PP SMMS
- Fabric weight: 25gsm
- Style: IL-2025YTUU
- Color: Yellow
- Size: Free size
- Packing: 10pcs/bag, 100pcs/carton (52*28*33 cm)
- G.W.: 6.7 KGS

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

AAMI Level 3 PP+PE 30gsm Isolation Gowns

- ✓ PPSB Coated PE materials provide excellent protection from liquid-borne microbes.
- ✓ Heat sealed seams with tape design provides high performance on hydrostatic pressure and fluids impact.
- ✓ Tie at the neck and waist for secure protection
- ✓ AAMI Level 3 protection (AAMI - Association for the Advancement of Medical Instrumentation)

- Material: 55% PP / 45% PE
- Fabric weight: 30gsm
- Style: IL3030YKTP
- Color: Yellow
- Size: Free size
- Packing: 100pcs/ carton (32x50x32cm)
- NW: 8.8kgs, GW:9.8kgs

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

AAMI Level 4 PP+PE 36gsm Isolation Gowns

- ✓ PPSB Coated PE materials provide excellent protection from liquid-borne microbes.
- ✓ Heat sealed seams with tape design provides high performance on hydrostatic pressure and fluids impact.
- ✓ Tie at the neck and waist for secure protection
- ✓ AAMI Level 4 protection (AAMI - Association for the Advancement of Medical Instrumentation)

- Material: 55% PP / 45% PE
- Fabric weight: 36gsm
- Style: IL4036YKTP
- Color: Yellow
- Size: Free size
- Packing: 100pcs/ carton (32x50x32cm)
- NW: 9.8kgs, GW:10.8kgs

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

AAMI Level 4 PP+PE 63gsm Isolation Gowns

Without Tape
(Level 4 on fabric)

With Tape

- ✓ PPSB laminated with PE film provide excellent protection from liquid-borne microbes.
- ✓ Comfortable and breathable fabric provides high performance on hydrostatic pressure and fluids impact.
- ✓ Tie at the neck and waist for secure protection
- ✓ AAMI Level 4 protection (AAMI - Association for the Advancement of Medical Instrumentation)
- ✓ Passed ASTM F1670, ASTM F1671

- Material: 55% PP / 45% PE
- Fabric weight: 63gsm
- Style: IL-4063WK / IL-4063WKTP
- Color: White
- Size: Free size
- Packing: 10pcs/bag, 100pcs/carton (50x32x45 cm)
- NW: 16kgs, GW: 17kgs

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

Disposable Chemo Gowns with Tape

- ✓ PPSB Coated PE materials provide excellent protection from liquid-borne microbes.
- ✓ Heat sealed seams with tape design provides high performance on hydrostatic pressure and fluids impact.
- ✓ Tie at the neck and waist for secure protection
- ✓ Pass ASTM F739-12 standard

- Material: 55% PP / 45% PE
- Fabric weight: 36gsm
- Style: IL-4036YKTP
- Color: Yellow
- Size: Free size
- Packing: 100pcs/ carton (32x50x32cm)
- NW: 9.8kgs, GW:10.8kgs

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

Disposable Chemo Gowns with Tape

- ✓ PPSB Coated PE materials provide excellent protection from liquid-borne microbes.
- ✓ Heat sealed seams with tape design provides high performance on hydrostatic pressure and fluids impact.
- ✓ Tie at the neck and waist for secure protection
- ✓ Pass ASTM F739-12 standard

- Material: 55% PP / 45% PE
- Fabric weight: 36gsm
- Style: IL-4063WKTP
- Color: White
- Size: Free size
- Packing: 100pcs/ carton (50x32x45 cm)
- NW: 16kgs, GW:17kgs

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

SMS Reinforced Disposable Surgical Gowns

- ✓ SMS reinforced gown, the chest and sleeve area are reinforced with additional layer of SMS material
- ✓ Meet ASTM F2407 standard
- ✓ Sterile style: EtO Sterilization followed by ISO 11135-1: 2007 standard
- ✓ Raglan sleeves, hook and loop neck closures, and tie waist closures
- ✓ Knitted cuff type
- ✓ AAMI Level 3 at reinforced area, and Level 1 at non-reinforced area

- Material: 100 % SMS
- Fabric weight: 45gsm
- Style: SG74100 Sterile
- Style: SG74700 Non Sterile
- Color: Blue
- Size: M, L, XL, XXL
- Packing: 25pcs/ carton

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

Spunlace Disposable Surgical Gowns

- ✓ Spunlace Regular gown is made by 100% Spunlace
- ✓ Spunlace reinforced gown, the chest and sleeve area are reinforced with additional layer of SMS material
- ✓ Meet ASTM F2407 standard
- ✓ Sterile style: EtO Sterilization followed by ISO 11135-1: 2007 standard
- ✓ Raglan sleeves, hook and loop neck closures, and tie waist closures
- ✓ Knitted cuff type
- ✓ AAMI Level 3 at reinforced area, and Level 1 at non-reinforced area

- Material: 100 % Spunlace
- Fabric weight: 45gsm
- Style: SG80100 Regular Sterile
- Style: SG80700 Regular Non-Sterile
- Style: SG84100 Reinforced Sterile
- Style: SG84700 Reinforced Non-Sterile
- Color: Blue
- Size: M, L, XL, XXL
- Packing: 25pcs/ carton

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

SFT Disposable Surgical Gowns

- ✓ Three-layer: fluid/blood-repellence PPSB and breathable Meltblown materials
- ✓ Meet ASTM F2407 standard
- ✓ Sterile style: EtO Sterilization followed by ISO 11135-1: 2007 standard
- ✓ Raglan sleeves, hook and loop neck closures, and tie waist closures
- ✓ Ultra-sonic welded seam
- ✓ Knitted cuff type
- ✓ AAMI Level 3 protection

- Material: PPSB + Flim+ Thermal Bond
- Fabric weight: 68gsm
- Style: SG94100 Sterile by EtO
- Style: SG94700 Non Sterile
- Color: Blue
- Size: M, L, XL, XXL
- Packing: 25pcs/ carton

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

Disposable Open Back PE gown

- ✓ 100% Polyethylene
- ✓ Convenient thumb loop on gown prevents sleeve slide-up
- ✓ High-level fluid protection

- Material: 100% Polyethylene
- Fabric weight: 23gsm
- Style: IL-0023LBTU
- Color: Light Blue
- Size: Free size
- Packing: 1pc/PE bag, 250pcs/ carton (63x31x37 cm)
- G.W.: 13.3 KGS

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

Reusable Isolation Gowns (AAMI Level 3 Fabrics)

- ✓ 100% polyester woven fabrics w/ PU coating or TPU laminated and water-repellent treatment.
- ✓ Tie at the neck and waist for secure protection
- ✓ Fabrics passed AAMI Level 3 test (AAMI - Association for the Advancement of Medical Instrumentation)

- Material: 100% Polyester
- Fabric weight: 60gsm / 75gsm / 105gsm
- Style: IL2060YK-R / IL2075YK-R / IL4105YK-R
- Color: Yellow
- Size: Free size
- Packing: 1pc/bag, 50pcs/carton

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

High Class Waterproof Breathable Protective Coverall with Hood

Passed Cat. III Type 5(B)/6(B), EN14126

- ✓ PPSB laminated PE
- ✓ Breathable and impervious
- ✓ Passed synthetic blood penetration resistance test
- ✓ Passed ASTM F1670, ASTM F1671 (higher standard than EN14126)
- ✓ Hood design provides overall protection
- ✓ With elastic wrist and open ankle

- Material PPSB laminated w/ breathable PE film
- Fabric weight: 63 gsm
- Style: IL-3063WEH
- Color: White
- Size: XS-XXXL.
- Packing: 50pcs/carton (57*40*35 cm)
- G.W.: 14-16 KGS
- Shelf life: 5 years

Size	Body Height (cm)	Chest Girth (cm)
S	162-170	84-92
M	168-176	92-100
L	174-182	100-108
XL	180-188	108-116
2XL	186-194	116-124
3XL	192-200	124-132

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

High Class Waterproof Breathable Protective Coverall with Hood & Tape

Passed Cat. III Type 4(B)/5(B)/6(B), EN14126

- ✓ PPSB laminated PE
- ✓ Breathable and impervious
- ✓ Passed synthetic blood penetration resistance test
- ✓ Passed ASTM F1670, ASTM F1671 (higher standard than EN14126)
- ✓ Hood design provides overall protection
- ✓ With elastic wrist and open ankle

- Material PPSB laminated w/ breathable PE film
- Fabric weight: 63 gsm
- Style: IL-3063WEHTP
- Color: White
- Size: XS-XXXL.
- Packing: 50pcs/carton (57*40*35 cm)
- G.W.: 14-16 KGS
- Shelf life: 5 years

Size	Body Height (cm)	Chest Girth (cm)
S	162-170	84-92
M	168-176	92-100
L	174-182	100-108
XL	180-188	108-116
2XL	186-194	116-124
3XL	192-200	124-132

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

CoverU Jacket (Flight Suit)

- ✓ To filter particles and dust
- ✓ The whole clothing is made of filtering materials; wearing it is equivalent to being protected under a large mask. (anti-fog)
- ✓ Comfortable to wear and has good air permeability

- Material: 100% PP SMMS
- Fabric weight: 50gsm
- Style: DC-0050WEH
- Color: White
- Size: M-4XL
- Packing: 50pcs/carton

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

ASTM Level 1 / Type IIR 3-Ply Face Mask

- Nonwoven Fabrics: 100% Polypropylene
  Nose wires: PVC or PE
  Earloop: 100% Nylon
- Packing : 50pcs/box, 2000pcs/carton

Style No.	FM-140G /FM-140B
Detailed product description	Face mask 3-ply (with elastic)
Color	Green/Blue
Product dimensions (cm)	17.5 x 9.3 cm ± 0.5cm
Bacterial filtration efficiency (BFE) (%)	≥ 98%
Synthetic Blood Penetration (Pressure: 120 mmHg)	Pass
Sub-micron Particle filtration efficiency (PFE) (%)	≥ 95% (0.1 micron)
Differential Pressure (mmH_2O/cm)	≦ 4.0
Differential Pressure (Pa/cm^2)	≦ 49.0
Microbial Cleanliness (cfu/g)	≦ 30
Flammability	No Ignition
Sterilization	Non sterile

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

ASTM Level 1 / Type IIR 3-Ply Face Mask

- Nonwoven Fabrics: 100% Polypropylene
  Nose wires: PVC or PE
  Earloop: 100% Nylon
- Packing : 50pcs/box, 2000pcs/carton

Our PPE For Your Complete Protection and Peace of Mind

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Disposable Children's Mask

5+ years 15.5 x 9.3 cm (6.10 x 3.66 inches)

2-4 years 13.5 x9.3 cm (5.31 x 3.66 inches)

- Nonwoven Fabrics: 100% Polypropylene
  Nose wires: PVC or PE
  Earloop: 100% Nylon
- Packing : 50pcs/box, 2000pcs/carton

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

ASTM F2100 Level 1 / Level 2 MADE IN USA

- Nonwoven Fabrics: 100% Polypropylene
  Nose wires: PVC or PE
  Earloop: 100% Nylon
- Packing : 50pcs/box, 2000pcs/carton

Detailed product description	Face mask 3-ply (with elastic)
Color	White
Product dimensions (cm)	17.5 x 9.3 cm ± 0.5cm
Bacterial filtration efficiency (BFE) (%)	≥ 98%
Synthetic Blood Penetration (Pressure: 120 mmHg)	Pass
Sub-micron Particle filtration efficiency (PFE) (%)	≥ 98% (0.1 micron)
Differential Pressure (mmH_2O/cm)	$\leqq 6.0$
Flammability	No Ignition
Sterilization	Non sterile

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

KN95 Mask

- ✓ Efficient filtration of PM2.5, bacteria and dust
- ✓ 3D stereo tailoring, excellent sealing and breathability

Detailed product description	Face mask 4-ply (with elastic)
Intended use	Respiratory protection
Color	White
Product dimensions (cm)	13 x 13 cm ± 0.5 cm
Sub-micron Particle filtration efficiency (PFE) (%)	≥ 95% (0.075µm NaCl, CMD)
Differential Pressure (mmH_2O/cm)	≦ 5
Flammability	No Ignition
Sterilization	Non sterile

- 4-ply with elastic (from outside to inside)
  - L1 : 100% Polypropylene
  - L2 : Melt-blown filter layer
  - L3 : 100% Polypropylene Anion process
  - L4 : 100% Polypropylene
- Nose wires: PE with Al Alloy
- Ear loop: 100% Nylon
- Packing : 1pc/polybag; 10pcs/box; 200pcs/carton
- Certifications: EN149:2001+A1:2009

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

3 Ply Reusable Protective Mask

- ✓ 3M Water-Repellent Fabric
- ✓ H1N1-Resistant Zinc Ion Antibacterial Treatment
- ✓ Anti-Pneumonias Sanitized Antibacterial Treatment
- ✓ SkinActive with Cool Feeling Textile

- 3-ply with elastic (from outside to inside)
  - L1 : 100% Polyester (Superfine Plain Woven Fabric)
  - L2 : 100% Polyester (Superfine Plain Woven Fabric)
  - L3 : 100% Nylon
- Style: RFM-260BK, RFM-260BL, RFM-260PK, RFM-260GY
- Color: Black, blue, pink and grey
- Packing : 1pc/polybag; 500pcs/carton

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

Safety Goggles

- ✓ Water-poof goggles help reduce exposure to a variety of eye hazards, including impact, splash and dust
- ✓ Features include indirect vents to protect against splash, and impact-resistant poly-carbonate lens that reduce UVB and UVA radiation by 99%

- Material:
  Lens: Polycarbonate
  Headband: Polyester
  Frame: PVC
- Packing : 1pc/polybag; 20pcs/inner box; 200pcs/carton
- Certifications: ANSI Z87.1 / CE EN166

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

Face Shield

- ✓ Anti-Fog, Anti-Splash and Anti-Static treatment
- ✓ Latex free, fiberglass free and distortion free
- ✓ Light weight and optically clear
- ✓ Do not use as protection against open flame or sparks

- Material: double sides Anti-fog PET
- Size: 32cm*22cm
- Packing : 1pc/bag; 200pcs/carton
- Certifications: FDA

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

Disposable Bouffant Caps

- ✓ Made of breathable, fluid-repellent PPSB
- ✓ Puffy shape, elastic design around the head for secure fit.

- Material: 100% PPSB / SMS
- Fabric weight: 14gsm / 15gsm
- Colors: White / Yellow
- Size:
  - White, 21” / 24”
  - Yellow, 21” / 24”
- Packaging: 100 ea / box, 1000 ea / pcs

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

Light Weight Shoe Cover

✓ Fluid-repellent

- Material: Polyethylene
- Fabric weight: 28gsm
- Colors: Blue
- Packing : 300pcs/carton

Anti-skid Shoe Cover

✓ Anti-skid printed

- Material: 100% PP SMS
- Fabric weight: 35gsm
- Colors: Ceil Blue
- Packing : 300pcs/carton

Our PPE For Your Complete Protection and Peace of Mind

Medtecs International Corporation Limited

Chairman, Mr. Clement Yang

CEO, Mr. William Yang

WHO WE ARE

Medtecs International Corporation Limited

- Professional Personal Protective Equipment (PPE) manufacturer for 30 years.
- 5,000 employees in Asia.
- Listed in Singapore and Taiwan.
- Largest supplier for DuPont (Tyvek Coverall).
- **Duty free to EU member countries, Canada & Australia!**

CORPORATE CULTURE

Medtecs International Corporation Limited

CORE VALUES

Customer Focus · Valuing Our People · Sustainable Practices

VISION

Providing world-class medical products, services and protective wear to ensure that every worker returns home safe.

MISSION

Providing safe, comfortable and stylish protective clothing and equipment for workers; providing support services with speed and soul to hospitals.

OUR COMPANY HISTORY

Medtecs International Corporation Limited

LAUNCH

1989

- Incorporated **Clement Textile & International Corporation** in the Philippines.

1994

- Incorporated **Universal Weavers Corporation** in the Philippines.

PUBLIC LISTED

1999

- **MEDTECS International Corporation Limited** was listed on the SGX-SESDAQ.
- Incorporated **MEDTECS (Cambodia) Corporation.**
- Incorporated **MEDTECS (Asia Pacific) Pte. Ltd.**

NEW LOCATION

2000

- Incorporated **MEDTECS (Taiwan) Corporation.**
- Acquired hospital laundry and sterilization business in Taiwan.

BSI & ISO-CERTIFIED WORK ENVIRONMENT

Medtecs International Corporation Limited

BSI & ISO-CERTIFIED WORK ENVIRONMENT

Medtecs (Cambodia) Corp, Ltd.

CSQ
www.imq.it

CISQ is a member of IQNet
The International Certification Network
www.iqnet-certification.com

IQNet, the association of the world's first class certification bodies, is the largest provider of management System Certification in the world.
IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N. 0242.2019
CERTIFICATE N.

SI CERTIFICA CHE IL SISTEMA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY SYSTEM OPERATED BY

MEDTECS (CAMBODIA) CORP, LTD.

PHUM AMPEL LEU, KHUM AMPEL, SROK KAMPONG - KAMPONG CHAM PROVINCE CAMBODIA

UNITA' OPERATIVE / *OPERATIVE UNITS*

PHUM AMPEL LEU, KHUM AMPEL, SROK KAMPONG - KAMPONG CHAM PROVINCE CAMBODIA

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 9001:2015

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Manufacture of textiles (including non woven) for clinical use including non sterile surgical gown, non sterile isolation gown, overshoes, non sterile container wrap, protective coverall, scrub garments, warmup garments, caps, surgical drape and shoes cover

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 9001:2015 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 9001:2015 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZIONE / *FIRST CERTIFICATION*	EMISSIONE CORRENTE / *CURRENT ISSUE*	SCADENZA / *EXPIRY*
	2010-06-24	2019-03-07	2022-06-24

IMQ S.p.A. - VIA QUINTILIANO, 43 - 20138 MILANO ITALY
Management Systems Division - Flavio Ornago

Le date di prima certificazione è riferita al rilascio da parte di altro Organismo
First certification date is related to issue date of another Certification Body

ACCREDIA
SQG N° 005 A

IAF: 04

IMQ
Organismo di Certificazione Federato CISQ
www.imq.it

FEDERAZIONE CISQ
www.cisq.com
CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

CSQ
www.imq.it

CISQ is a member of IQNet
The International Certification Network
www.iqnet-certification.com

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IQNet is composed of more than 30 bodies and counts over 150 subsidiaries all over the globe.

CERTIFICATO N. 0451.2019
CERTIFICATE N.

SI CERTIFICA CHE IL SISTEMA QUALITA' DI
WE HEREBY CERTIFY THAT THE QUALITY SYSTEM OPERATED BY

MEDTECS (CAMBODIA) Corp., Ltd.

PHUM AMPEL LEU, KHUM AMPEL, SROK KAMPONG SIEM, KAMPONG CHAM PROVINCE, CAMBODIA

UNITA' OPERATIVE / *OPERATIVE UNITS*

PHUM AMPEL LEU, KHUM AMPEL, SROK KAMPONG SIEM, KAMPONG CHAM PROVINCE, CAMBODIA

E' CONFORME ALLA NORMA / *IS IN COMPLIANCE WITH THE STANDARD*

ISO 13485:2016

PER LE SEGUENTI ATTIVITA' / *FOR THE FOLLOWING ACTIVITIES*

Manufacture of antistatic surgical gown, isolation gown, protective coverall, surgical gown, patient gown, scrub suit, nurse uniform, blanket, flat sheet, bed cover, pillow case, towel, lab coat, wrapper, shoe cover, underpad, face mask, pajamas, nightdress, transfer sheet, surgeon hood, laundry bag, warm up jacket, drawstring pants, medical garment, dental gown.

Ulteriori informazioni riguardanti l'applicabilità dei requisiti ISO 13485:2016 possono essere ottenute consultando l'organizzazione
Further clarifications regarding the applicability of ISO 13485:2016 requirements may be obtained by consulting the organization

IL PRESENTE CERTIFICATO E' SOGGETTO AL RISPETTO DEL REGOLAMENTO PER LA CERTIFICAZIONE DEI SISTEMI DI GESTIONE
THE USE AND THE VALIDITY OF THE CERTIFICATE SHALL SATISFY THE REQUIREMENTS OF THE RULES FOR CERTIFICATION OF MANAGEMENT SYSTEMS

DATE:	PRIMA CERTIFICAZION / *FIRST CERTIFICATIO*	EMISSIONE CORRENTE / *CURRENT ISSUE*	SCADENZA / *EXPIRY*
	2019-03-25	2019-03-25	2022-03-24

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Management Systems Division - Flavio Ornago

ACCREDIA
SQG N° 005 A

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FEDERAZIONE CISQ
www.cisq.com
CISQ è la Federazione Italiana di Organismi di Certificazione dei sistemi di gestione aziendale.
CISQ is the Italian Federation of management system Certification Bodies.

BSI & ISO-CERTIFIED WORKPLACE

Medtecs International Corporation Limited

bsi.

By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 13485:2016

This is to certify that: Medtecs Materials Technology Corp.
/Medtex Corporation
7th St., Phase II,
Freeport Area of Bataan,
Mariveles, Bataan
2106
Philippines

Holds Certificate Number: **MD 500825**

and operates a Quality Management System which complies with the requirements of ISO 13485:2016 for the following scope:

The manufacture of incontinence protective restraint garment, surgical garment, surgical drapes, elastic bandage, therapeutic medical binder, mattress cover, operation room bed linens, examination garment, surgical face mask.

For and on behalf of BSI:

Gary E Slack, Senior Vice President - Medical Devices

Original Registration Date: 2005-10-28
Latest Revision Date: 2020-09-30

Effective Date: 2020-10-07
Expiry Date: 2023-10-06

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By Royal Charter

Certificate of Registration

QUALITY MANAGEMENT SYSTEM - ISO 9001:2015

This is to certify that: Medtecs Materials Technology Corp.
/Medtex Corporation
7th St., Phase II,
Freeport Area of Bataan,
Mariveles, Bataan
2106
Philippines

Holds Certificate No: **FM 501307**

and operates a Quality Management System which complies with the requirements of ISO 9001:2015 for the following scope:

The manufacture of protective restraint garment, surgical garment, surgical drapes, elastic bandage, therapeutic medical binder, mattress cover, operation room bed linens, examination garment, face mask.

For and on behalf of BSI:

Chris Cheung, Head of Compliance & Risk - Asia Pacific

Original Registration Date: 2005-10-21
Latest Revision Date: 2020-09-25

Effective Date: 2020-10-07
Expiry Date: 2023-10-06

Page: 1 of 2

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Taiwan Headquarters: 2nd Floor, No.37, Ji-Hu Rd., Nei-Hu Dist., Taipei 114, Taiwan, R.O.C.
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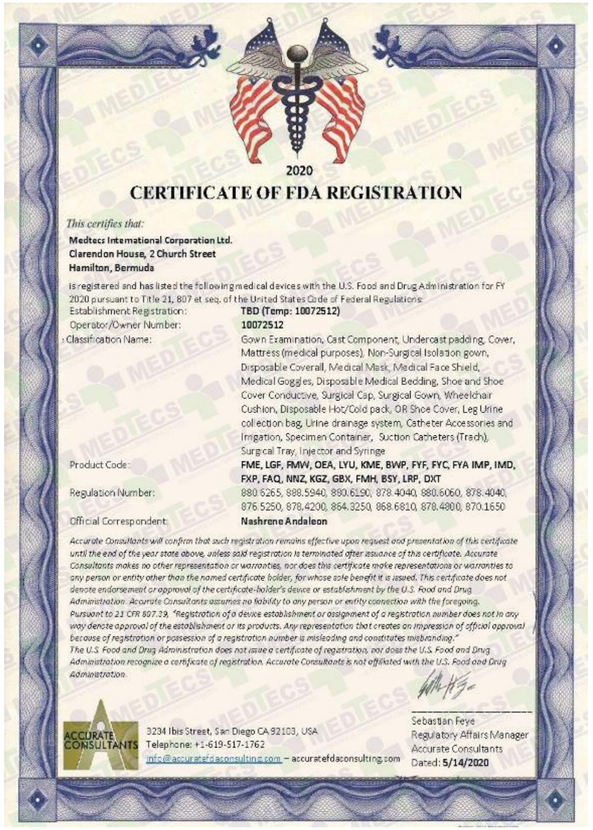
FDA CERTIFICATES

Medtecs International Corporation Limited



2020

CERTIFICATE OF FDA REGISTRATION

This certifies that:

Medtecs International Corporation Ltd.
Clarendon House, 2 Church Street
Hamilton, Bermuda

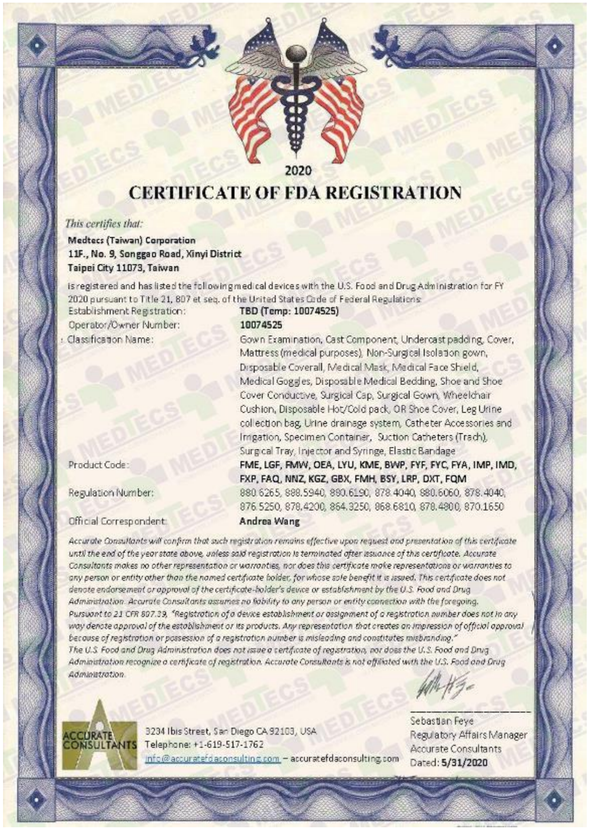
is registered and has listed the following medical devices with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Registration:	**TBD (Temp: 10072512)**
Operator/Owner Number:	**10072512**
Classification Name:	Gown Examination, Cast Component, Undercast padding, Cover, Mattress (medical purposes), Non-Surgical Isolation gown, Disposable Coverall, Medical Mask, Medical Face Shield, Medical Goggles, Disposable Medical Bedding, Shoe and Shoe Cover Conductive, Surgical Cap, Surgical Gown, Wheelchair Cushion, Disposable Hot/Cold pack, OR Shoe Cover, Leg Urine collection bag, Urine drainage system, Catheter Accessories and Irrigation, Specimen Container, Suction Catheters (Trach), Surgical Tray, Injector and Syringe
Product Code:	**FME, LGF, FMW, OEA, LYU, KME, BWP, FYF, FYC, FYA IMP, IMD, FXP, FAQ, NNZ, KGZ, GBX, FMH, BSY, LRP, DXT**
Regulation Number:	880.6265, 888.5940, 880.6190, 878.4040, 880.6060, 878.4040, 876.5250, 878.4200, 864.3250, 868.6810, 878.4800, 870.1650
Official Correspondent:	**Nashrene Andaleon**

Accurate Consultants will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year state above, unless said registration is terminated after issuance of this certificate. Accurate Consultants makes no other representation or warranties, nor does this certificate make representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Accurate Consultants assumes no liability to any person or entity connection with the foregoing.
Pursuant to 21 CFR 807.39, "Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."
The U.S. Food and Drug Administration does not issue a certificate of registration, nor does the U.S. Food and Drug Administration recognize a certificate of registration. Accurate Consultants is not affiliated with the U.S. Food and Drug Administration.

ACCURATE CONSULTANTS
3234 Ibis Street, San Diego CA 92103, USA
Telephone: +1-619-517-1762
info@accuratefdaconsulting.com – accuratefdaconsulting.com

Sebastian Feye
Regulatory Affairs Manager
Accurate Consultants
Dated: **5/14/2020**



2020

CERTIFICATE OF FDA REGISTRATION

This certifies that:

Medtecs (Taiwan) Corporation
11F., No. 9, Songgao Road, Xinyi District
Taipei City 11073, Taiwan

is registered and has listed the following medical devices with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Registration:	**TBD (Temp: 10074525)**
Operator/Owner Number:	**10074525**
Classification Name:	Gown Examination, Cast Component, Undercast padding, Cover, Mattress (medical purposes), Non-Surgical Isolation gown, Disposable Coverall, Medical Mask, Medical Face Shield, Medical Goggles, Disposable Medical Bedding, Shoe and Shoe Cover Conductive, Surgical Cap, Surgical Gown, Wheelchair Cushion, Disposable Hot/Cold pack, OR Shoe Cover, Leg Urine collection bag, Urine drainage system, Catheter Accessories and Irrigation, Specimen Container, Suction Catheters (Trach), Surgical Tray, Injector and Syringe, Elastic Bandage
Product Code:	**FME, LGF, FMW, OEA, LYU, KME, BWP, FYF, FYC, FYA, IMP, IMD, FXP, FAQ, NNZ, KGZ, GBX, FMH, BSY, LRP, DXT, FQM**
Regulation Number:	880.6265, 888.5940, 880.6190, 878.4040, 880.6060, 878.4040, 876.5250, 878.4200, 864.3250, 868.6810, 878.4800, 870.1650
Official Correspondent:	**Andrea Wang**

Accurate Consultants will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year state above, unless said registration is terminated after issuance of this certificate. Accurate Consultants makes no other representation or warranties, nor does this certificate make representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Accurate Consultants assumes no liability to any person or entity connection with the foregoing.
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Sebastian Feye
Regulatory Affairs Manager
Accurate Consultants
Dated: **5/31/2020**

2020

CERTIFICATE OF FDA REGISTRATION

This certifies that:

Medtecs (Cambodia) Corp., Ltd.
No. 62 Street, 348 Sangkat Toul
Svay Prey 2, Khan Chamkamorn
Phnom Penh, KH 2106

is registered and has listed the following medical device with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Registration:	**3003826906**
Operator/Owner Number:	**9051387**
Device Classification Name:	Gown Examination, Cast Component, Undercast padding, Cover, Mattress (medical purposes), Non-Surgical Isolation gown, Disposable Coverall, Accessory, Surgical Apparel, Disposable Medical Bedding, Shoe and Shoe Cover Conductive, Surgical Cap, Incontinence Pads/Underpad
Product Code:	**FME, LGF, FMW, OEA, LYU, KME, BWP, FYF, EYQ**
Regulation Number:	880.6265, 888.5940, 880.6190, 878.4040, 880.6060, 876.5920
Official Correspondent:	**Maria Fatima P Alipio**

Accurate Consultants will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year state above, unless said registration is terminated after issuance of this certificate. Accurate Consultants makes no other representation or warranties, nor does this certificate make representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Accurate Consultants assumes no liability to any person or entity connection with the foregoing.
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Sebastian Feye
Regulatory Affairs Manager
Accurate Consultants
Dated: **4/8/2020**

2020

CERTIFICATE OF FDA REGISTRATION

This certifies that:

Medtex Corporation
7th Street, Phase 2, AFAB
Mariveles, Bataan, 2105
Philippines

is registered and has listed the following medical device with the U.S. Food and Drug Administration for FY 2020 pursuant to Title 21, 807 et seq. of the United States Code of Federal Regulations:

Establishment Registration:	**TBD**
Operator/Owner Number:	**10068000**
Device Classification Name:	Disposable Medical Mask (non-sterile), Disposable Medical Mask, Protective Mask, Abdominal Binder, Bandage, Elastic, Disposable Isolation Gown, Patient Gown, Exam Gown, ISO Gown
Product Code:	**LYU, FQM, OEA, FME**
Regulation Number:	878.4040, 880.5075, 880.6265
Official Correspondent:	**Nashrene Andaleon**

Accurate Consultants will confirm that such registration remains effective upon request and presentation of this certificate until the end of the year state above, unless said registration is terminated after issuance of this certificate. Accurate Consultants makes no other representation or warranties, nor does this certificate make representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. Accurate Consultants assumes no liability to any person or entity connection with the foregoing.
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Sebastian Feye
Regulatory Affairs Manager
Accurate Consultants
Dated: **4/7/2020**

Presence at International Trade Shows

Medtecs International Corporation Limited

IDEA Trade Show (2019.03)

A+A Trade Show (2019.11)

1. Strong Sourcing Ability
2. On-Time Performance
3. Logistics
4. Short Leadtime
5. Flexible Capacity
6. Certified Work Environment
7. 30 Years in the Field

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