GREAT ECO GLOVE SDN BHD (970327-V)

DECLARATION OF CONFORMITY (DOC)

EXAMINATION GLOVES LATEX POWDER FREE NITRILE POWDER FREE (NON-STERILE)

Lot 1675, Jalan Makmur, Batu 28, IJOK 45600 BESTARI JAYA, Selangor D.E., MALAYSIA
Tel: +6018 3654144, +603 32792199 Fax: +603 78865199 Email: world.geg@gmail.com

GREAT ECO GLOVE SDN BHD (970327-V)

DECLARATION OF CONFORMITY

Manufacturer Name	GREAT ECO GLOVE SDN BHD
Manufacturer Address	LOT 1675, JALAN MAKMUR, BATU 28, IJOK, 45600 BESTARI JAYA, SELANGOR DARUL EHSAN, MALAYSIA
Product Name	EXAMINATION GLOVE (NON-STERILE), LATEX POWER FREE, NITRILE POWDER FREE
Device Classification	Class I, Rule 5
Product Code	EXGL
Conformity Assessment Route	This declaration is based on conformity assessment procedure of Medical Device Directive 93/42/EEC, Annex VII.
Applied Standards	ISO 13485:2016 –Medical Devices-Quality Management Systems Medical Device Directive 93/42/EEC, Annex VII EN ISO 14971:2012 –Medical Device-Application of Risk Management to medical devices EN ISO 15223-1:2016 –Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied EN 455-1:2000 – Medical Gloves for Single use. Requirements and testing for freedom from holes EN455-2:2015 – Medical Gloves for Single Use. Requirements and testing or physical properties EN 455-3:2006 – Medical Gloves for Single Use. Requirements and testing for biological evaluation EN 455-4:2009 – Medical Gloves for Single Use. Requirements and testing for Shelf-life determination
Quality Management System, QMS	ISO 13485:2016 – Medical Device Quality Management System Kgs Certification Sdn Bhd Certificate No: 510182 Validty: 05 November 2018 Till 04 November 2021

Lot 1675, Jalan Makmur, Batu 28, IJOK 45600 BESTARI JAYA, Selangor D.E., MALAYSIA
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GREAT ECO GLOVE SDN BHD (970327-V)

Certifying Body Name	MEDCER ULUSLARARASI MEDIKAL BELGELENDIME ANONIM ŞIRKETI, TAŞPINAR MAH, 2800 CAD. A-2 APT. NO.6/49 GÖLBAŞI/ANKARA TURKEY
CE Details	CE Certificate Number: MD 120520/01 Report Number: 12052020.01 Issued by: MEDCER ULUSLARARASI MEDIKAL BELGELENDIME ANONIM ŞIRKETI, TURKEY Validity: 12/05/2020 – 11/05/2020

I, DR. NEOH VEE HENG (GREAT ECO GLOVE SDN BHD), the manufacturer, declare and ensure with sole responsibility that products listed above meet the applicable requirements of the Medical Device Directive 93/42/EEC, Annex VII.

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DR. NEOH VEE HENG
EXECUTIVE DIRECTOR
GREAT ECO GLOVE SDN BHD
23rd May 2020

Lot 1675, Jalan Makmur, Batu 28, IJOK 45600 BESTARI JAYA, Selangor D.E., MALAYSIA
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GREAT ECO GLOVE SDN BHD (970327-V)

DECLARATION OF CONFORMITY (DOC)

EXAMINATION GLOVES LATEX POWDER FREE NITRILE POWDER FREE (NON-STERILE)

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GREAT ECO GLOVE SDN BHD (970327-V)

DECLARATION OF CONFORMITY

Manufacturer Name	GREAT ECO GLOVE SDN BHD
Manufacturer Address	LOT 1675, JALAN MAKMUR, BATU 28, IJOK, 45600 BESTARI JAYA, SELANGOR DARUL EHSAN, MALAYSIA
Product Name	EXAMINATION GLOVE (NON-STERILE), LATEX POWER FREE, NITRILE POWDER FREE
Device Classification	Class I, Rule 5
Product Code	EXGL
Conformity Assessment Route	This declaration is based on conformity assessment procedure of Medical Device Directive 93/42/EEC, Annex VII.
Applied Standards	ISO 13485:2016 –Medical Devices-Quality Management Systems Medical Device Directive 93/42/EEC, Annex VII EN ISO 14971:2012 –Medical Device-Application of Risk Management to medical devices EN ISO 15223-1:2016 –Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied EN 455-1:2000 – Medical Gloves for Single use. Requirements and testing for freedom from holes EN455-2:2015 – Medical Gloves for Single Use. Requirements and testing or physical properties EN 455-3:2006 – Medical Gloves for Single Use. Requirements and testing for biological evaluation EN 455-4:2009 – Medical Gloves for Single Use. Requirements and testing for Shelf-life determination
Quality Management System, QMS	ISO 13485:2016 – Medical Device Quality Management System Kgs Certification Sdn Bhd Certificate No: 510182 Validty: 05 November 2018 Till 04 November 2021

Lot 1675, Jalan Makmur, Batu 28, IJOK 45600 BESTARI JAYA, Selangor D.E., MALAYSIA
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GREAT ECO GLOVE SDN BHD (970327-V)

Certifying Body Name	MEDCER ULUSLARARASI MEDIKAL BELGELENDIME ANONIM ŞIRKETI, TAŞPINAR MAH, 2800 CAD. A-2 APT. NO.6/49 GÖLBAŞI/ANKARA TURKEY
CE Details	CE Certificate Number: MD 120520/01 Report Number: 12052020.01 Issued by: MEDCER ULUSLARARASI MEDIKAL BELGELENDIME ANONIM ŞIRKETI, TURKEY Validity: 12/05/2020 – 11/05/2020

I, DR. NEOH VEE HENG (GREAT ECO GLOVE SDN BHD), the manufacturer, declare and ensure with sole responsibility that products listed above meet the applicable requirements of the Medical Device Directive 93/42/EEC, Annex VII.

.....

DR. NEOH VEE HENG
EXECUTIVE DIRECTOR
GREAT ECO GLOVE SDN BHD
23rd May 2020

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GREAT ECO GLOVE SDN BHD (970327-V)

DECLARATION OF CONFORMITY

This declaration is based on conformity assessment procedure of Medical Device Directive 93/42/EEC, Annex VII.

I, *Dr Neoh Vee Heng* hereby declare and ensure with sole responsibility that the below mentioned device meet the applicable requirement of Medical Device Directive 93/42/EEC, Annex VII.

Particulars of device

Generic name:	Examination Glove (Non-Sterile)
Manufacturer:	Great Eco Glove Sdn Bhd (970327-V)
Manufacturing site:	Lot 1675, Jalan Makmur, Batu 28, Ijok,
	45600, Bestari Jaya, Selangor, Malaysia
Device classification:	Class I, Rule 5
Product Code:	EXGL

Quality Management System certificate ("QMS")

Conformity Assessment Body issuing the certificate:	KGS Certification Sdn. Bhd.
Certificate number:	510182
Issuance date:	05 November 2018
Expiry date:	04 November 2021

Lot 1675, Jalan Makmur, Batu 28, Ijok 45600 Bestari Jaya, Selangor D.E., MALAYSIA
Tel: +6018 3654 144, +60332792199 Fax: +603 7886 5199 Email: world.geg@gmail.com

GREAT ECO GLOVE SDN BHD (970327-V)

List of applied standard

ISO 13485:2016 - Medical Device- Quality Management Systems

EN ISO 14971:2012 – Medical Device-Application of Risk Management to medical devices

EN ISO 15223-1:2016 – Medical Devices-Symbols to be used with medical device labels, labelling and information to be supplied

EN 455-1:2000 – Medical Gloves for Single use. Requirements and testing for freedom from holes

EN455-2:2015 – Medical Gloves for Single Use. Requirements and testing or physical properties

EN 455-3:2006 – Medical Gloves for Single Use. Requirements and testing for biological evaluation

EN 455-4:2009 – Medical Gloves for Single Use. Requirements and testing for Shelf-life determination

Authorised Signatory:

GREAT ECO GLOVE 970327-V * SDN. BHD. *

Dr Neoh Vee Heng

Executive Chairman

1/08/2020

Lot 1675, Jalan Makmur, Batu 28, Ijok 45600 Bestari Jaya, Selangor D.E., MALAYSIA
Tel: +6018 3654 144, +60332792199 Fax: +603 7886 5199 Email: world.geg@gmail.com

GREAT ECO GLOVE SDN BHD (970327-V)

DECLARATION OF CONFORMITY

This declaration is based on conformity assessment procedure of *Personal Protective Equipment Regulation (EU) 2016/425 – Module B (Annex V), Module D (annex VII).*

I, *Dr Neoh Vee Heng* hereby declare and ensure with sole responsibility that the below mentioned device meet the applicable requirement of Regulation (EU) 2016/425 – Module B, Annex V and Module D, Annex VII.

Particulars of device

Generic name:	Examination Glove
Manufacturer:	Great Eco Glove Sdn Bhd (970327-V)
Manufacturing site:	Lot 1675, Jalan Makmur, Batu 28, Ijok,
	45600, Bestari Jaya, Selangor, Malaysia
Device classification:	Category III

Quality Management System certificate ("QMS")

Conformity Assessment Body issuing the certificate:	KGS Certification Sdn. Bhd.
Certificate number:	510182
Issuance date:	05 November 2018
Expiry date:	04 November 2021

GREAT ECO GLOVE SDN BHD (970327-V)

List of applied standard

(a) ISO 13485:2016 –Medical Devices-Quality Management Systems
(b) PPE Regulation (EU) 2016/425 – Module B (Annex V)
(c) EN ISO 21420:2020 – Protective Gloves. General requirements and test methods
(d) Protective gloves against dangerous chemicals and micro-organisms
    a. EN 374-1:2016 – Terminology and performance requirements for chemical risks
        i. 40% Sodium hydroxide
        ii. 37% Formaldehyde
    b. EN 374-2:2014 – Determining resistance to penetration
    c. ISO 16523-1:2015 – Chemical permeation testing of gloves
    d. EN 374-4:2013 – Determination of resistance to degradation by chemicals
    e. EN 374-5:2016 – Terminology and performance requirement for micro-organism risks
    f. ISO 16604:2004 – Clothing for protection against contact with blood and body fluids – Determination of resistance of protective clothing materials to penetration by blood-borne pathogens – Test method using Phi-X 174 bacteriophage

Notifying Body

BSI Group the Netherlands B.V. (NB 2797)

Authorised Signatory:

GREAT ECO GLOVE 970327-V * SDN. BHD. *

Dr Neoh Vee Heng

Executive Chairman

1/08/2020

Lot 1675, Jalan Makmur, Batu 28, Ijok 45600 Bestari Jaya, Selangor D.E., MALAYSIA
Tel: +6018 3654 144, +60332792199 Fax: +603 7886 5199 Email: world.geg@gmail.com

GREAT ECO GLOVE SDN BHD (970327-V)

DECLARATION OF CONFORMITY

This declaration is based on conformity assessment procedure of *Personal Protective Equipment Regulation (EU) 2016/425 – Module B (Annex V), Module C2 (annex VII).*

I, *Dr Neoh Vee Heng* hereby declare and ensure with sole responsibility that the below mentioned device meet the applicable requirement of Regulation (EU) 2016/425 – Module B, Annex V and Module C2, Annex VII.

Particulars of device

Generic name:	9NPF Nitrile Examination Gloves
Manufacturer:	Great Eco Glove Sdn Bhd (970327-V)
Manufacturing site:	Lot 1675, Jalan Makmur, Batu 28, Ijok,
	45600, Bestari Jaya, Selangor, Malaysia
Module B Certificate number:	CE 735448
Module C2 Certificate number:	CE 738460
Device classification:	Category III

Quality Management System certificate ("QMS")

Conformity Assessment Body issuing the certificate:	KGS Certification Sdn. Bhd.
Certificate number:	510182
Issuance date:	05 November 2018
Expiry date:	04 November 2021

GREAT ECO GLOVE SDN BHD (970327-V)

List of applied standard

(a) EN ISO 21420:2020 – Protective Gloves. General requirements and test methods

(b) Protective gloves against dangerous chemicals and micro-organisms

a. EN 374-1:2016 – Terminology and performance requirements for chemical risks
   i. 40% Sodium hydroxide
   ii. 37% Formaldehyde

b. EN 374-2:2014 – Determining resistance to penetration

c. ISO 16523-1:2015 – Chemical permeation testing of gloves

d. EN 374-4:2013 – Determination of resistance to degradation by chemicals

e. EN 374-5:2016 – Terminology and performance requirement for micro-organism risks

f. ISO 16604:2004 – Clothing for protection against contact with blood and body fluids – Determination of resistance of protective clothing materials to penetration by blood-borne pathogens – Test method using Phi-X 174 bacteriophage

Notifying Body

The details of the Notified body responsible for EU type examination (Module B) set out in Annex V and conformity to type based on internal production control plus supervised product checks at random intervals (Module C2) set out in Annex VII are as follow:

Name:	BSI Group the Netherlands B.V.
Address:	Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam
Country:	Netherlands
Phone:	+31 (0)20 346 07 80
Email:	info.nl@bsigroup.com
Notified Body number:	2797

Authorised Signatory:

Dr Neoh Vee Heng

Executive Chairman

1/10/2020