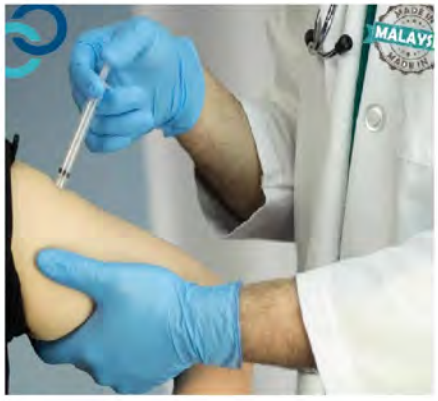
Disposable Examination Glove

NITRILE EXAMINATION GLOVES, POWDER FREE

- Brand Name: AXGLOVE
- Model Number: G002 (Powder Free)
- Size: XS,S,M,L,XL
- Application: Cleaning, Examination Use, Food, General Usage, Laboratory



LATEX EXAMINATION GLOVES, POWDERED

- Brand Name: AXGLOVE
- Model Number: G001 (Powdered)
- Colour: White
- Size: XS,S,M,L,XL
- Application: Examination Use, General Usage

No. Siri: **004076**
Serial No.:

ASAL
ORIGINAL

PIHAK BERKUASA
PERANTI PERUBATAN

MEDICAL DEVICE AUTHORITY

PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY
AKTA PERANTI PERUBATAN 2012 (AKTA 737)
MEDICAL DEVICE ACT 2012 (ACT 737)
LESEN ESTABLISMEN
ESTABLISHMENT LICENCE
Seksyen 15(1) Akta 737
Section 15(1) of Act 737

No. Lesen: **KP88793210518**
License No.:

Tarikh Sah Lesen: **26/09/2018**
License Validity Date: **25/09/2021**

Lesen adalah dengan ini diberi kepada:
Licence is hereby granted to:

AXG INDUSTRIES SDN BHD

yang beralamat di:
of

NO 17, LORONG SULTAN MOHAMED 25D/KU18 ,
TAMAN PERINDUSTRIAN BANDAR SULTAN SULAIMAN ,
42000 PELABUHAN KLANG, SELANGOR
42000 SELANGOR

Sebagai:
as

PENGEDAR
DISTRIBUTOR

Orang yang bertanggungjawab: **YEOH CHEN KUAN (I/C: 820815075067)**
Person Responsible:

Lesen ini diberikan tertakluk kepada peruntukan-peruntukan di bawah Akta 737 dan peraturan-peraturan dibawahnya serta syarat-syarat seperti di Lampiran 1.
This licence is granted subject to the provisions under Act 737 and its subsidiary legislations and the conditions as in Attachment 1.

AHMAD SHARIFF BIN HAMBALI
Ketua Eksekutif
Chief Executive
PIHAK BERKUASA PERANTI PERUBATAN
MEDICAL DEVICE AUTHORITY

CARE
Certification International

2018 2019 2020



Certificate No. : MYMD10184339

This certificate has been

Awarded to

AXG INDUSTRIES SDN BHD 927814W

Which is located at

NO. 17, LORONG SULTAN MOHAMED 25D/KU18, TAMAN PERINDUSTRIAN BANDAR SULTAN SULEIMAN, 42000 PELABUHAN KLANG, SELANGOR, MALAYSIA.

On Standard

ISO 13485 : 2016

Which the organization stated above had been assessed and found to be in accordance with the requirements of international Quality Management System for Medical Device.

Under the Scope of

SUPPLY OF NATURAL LATEX AND NITRILE EXAMINATION GLOVES FOR MEDICAL DEVICE.

Original Issued Date	:	**10th October 2018**
Effective Date	:	**10th October 2018**
Expiration Date	:	**9th October 2021**

This certificate will be null and void if at any circumstances the compliance towards the standards of ISO 17021 is not fulfilled. The compliance of the standards stated above will be indicated by the labelling on the right corner indicating the year of assessment. The validity of the certificate can also be traced to the audit report generated for each every assessment or through our website www.carecert.net

STANDARDS MALAYSIA
ACCREDITED CERTIFICATION BODY

MDQMS 29042015 CB 03

CARE

Fleming Teo
Managing Director
CARE Certification International (M) Sdn. Bhd.

CARE
Certification International

2018 2019 2020

Valid with sticker ONLY

Certificate No. : MYQ6183893

This certificate has been

Awarded to

AXG INDUSTRIES SDN BHD 927814W

Which is located at

NO. 17, LORONG SULTAN MOHAMED 25D/KU18, TAMAN PERINDUSTRIAN BANDAR SULTAN SULEIMAN, 42000 PELABUHAN KLANG, SELANGOR, MALAYSIA.

On Standard

ISO 9001 : 2015

Which the organization stated above had been assessed and found to be in accordance with the requirements of international Quality Management System.

Under the Scope of

PROVISION OF INDUSTRIES GLOVE SUPPLY SERVICE.

Original Issued Date	:	**25th June 2015**
Effective Date	:	**20th June 2018**
Expiration Date	:	**24th June 2021**

This certificate will be null and void if at any circumstances the compliance towards the standards of ISO 17021 is not fulfilled. The compliance of the standards stated above will be indicated by the labelling on the right corner indicating the year of assessment. The validity of the certificate can also be traced to the audit report generated for each every assessment or through our website www.carecert.net

STANDARDS MALAYSIA ACCREDITED CERTIFICATION BODY

QS 02032013 CB 13

MEMBER OF MULTILATERAL RECOGNITION ARRANGEMENT IAF

Fleming Teo
Managing Director
CARE Certification International (M) Sdn. Bhd.

obelis
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

CERTIFICATE OF CE (MDD) NOTIFICATION

Ref. No.: CH 2468-2013

Date: 11/12/2013

Order No.: CH 2054-2013

THIS IS TO CERTIFY THAT, ACCORDING TO THE EUROPEAN COUNCIL DIRECTIVE 93/42/EEC WE, HERE AT OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

NAME: AXG INDUSTRIES SDN BHD

ADDRESS: NO 17, LORONG SULTAN MOHAMED 25D/KU18,TAMAN PERINDUSTRIAN BANDAR SULTAN SULEIMAN,42000 PELABUHAN KLANG, MALAYSIA

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the Class I * devices comply with the Directive including all essential requirements.

The Manufacturer has provided Obelis s.a. (O.E.A.R.C.) with all the appropriate declarations as per the European Council Directive 93/42/EEC article 14 requirements, including the EC Declaration of Conformity (according to Annex VII) confirming that their Class I medical devices, as stipulated here above, are fulfilling the applicable requirements of the European Council Directive 93/42/EEC.

The notification of the following medical devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 06/12/2013 in compliance with the European Council Directive 93/42/EEC and 2007/47/EC - article 14 requirements.

CLASS I MEDICAL DEVICE(S): PLEASE SEE ANNEX A - LIST OF DEVICES (1 PAGE, 4 DEVICES)

As of the 07/12/2013, and as long as the Manufacturer will continue complying with the hereaboye mentioned requirements**, he therefore:

- Is required to affix the CE marking on these devices;
- May place these devices in the European community Territory.

OBELIS S.A. - O.E.A.R.C.
Registered address
Bd Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

Mr. G. Elkaym CEO
Obelis sa
date & stamp

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
17-12-2013
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

Brussels Enterprise
Commerce & Industry
date & stamp

SEEN
by the Brussels Chamber of Commerce
17 DEC. 2013
Brussels, the

Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2008 and ISO 13485 : 2003 certified in accordance to the profession of a European Authorized Representative.

*also applicable to Class I s & m
** and provided that the product classification will not be rejected by the competent authorities