CERTIFICATE

This is to certify that

[redacted]
Malaysia.

has implemented and maintains a **Quality Management System**.

Scope:
Manufacturing of Medical Examination Gloves.

Through an audit, documented in a report, it was verified that the management system fulfills the requirements of the following standard:

ISO 13485 : 2016

Certificate registration no.	510309 MP2016
Date of certification	2019-01-17
Valid until	2022-01-16

STANDARDS MALAYSIA
ACCREDITED CERTIFICATION BODY
MDQMS 20012015 CB 02

DQS Certification (M) Sdn Bhd

Danny Ng
Regional Managing Director

Accredited Body: DQS Malaysia, Suite 43-4 Setia Avenue, Jalan Setia Prima S U 13/S, Setia Alam Seksyen U 13, 40170 Shah Alam, Selangor - Malaysia

Member of IQNet
THE INTERNATIONAL CERTIFICATION NETWORK

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
KAMER VAN KOOPHANDEL

Obelis SA
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
26 -05- 2016
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

EUROPEAN RESPONSIBLE PERSON CENTER
Obelis
SINCE 1988

CERTIFICATE OF CE (MDD) NOTIFICATION

Ref. No.: MC 4810-2016

Date: 24/05/2016

Order No.: MC 4470-2015

THIS IS TO CERTIFY THAT, ACCORDING TO THE 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: [redacted] SDN BHD

ADDRESS: LOT [redacted] MALAYSIA

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the Class I * device complies 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 Council Directive 93/42/EEC article 14 requirements, including the EC Declaration of Conformity (according to Annex VII) confirming that their Class I medical device, as stipulated here below, is fulfilling the applicable requirements of the Council Directive 93/42/EEC.

The notification of the following medical device(s) has been completed by Obelis s.a. (O.E.A.R.C.) on the 04/05/2016 in compliance with the Council Directive 93/42/EEC - article 14 requirements.

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

As of the 05/05/2016, and as long as the Manufacturer will continue complying with the hereabove mentioned requirements**, he therefore:

- Is required to affix the CE marking on this device;

- May place this device in the European EU and EEA territory,

SEEN
by the Brussels Chamber of Commerce
Nastasja OTTE

P.O. S. FERRETTI C.C.O.

Mr. G. Elkayam CEO
Obelis sa
date & stamp

Obelis s.a.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles

Brussels, the 26 MAI 2016

Brussels Enterprise
Commerce & Industry
date & stamp

Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

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

Ref. no.: MC 4810-2016
Order No.: MC 4470-2015

Annex A* – List of devices

(Article 9, section 1 of the Directive 93/42/EEC on medical devices)

No.	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN code	Class**	Rule
1	N/A	Latex Examination Gloves	Medical Examination Gloves	Medical Examination Gloves are to be used by covering user's hands / Donning by inserting the hand inside the gloves. Medical Examination Gloves are meant for single use only.	47173	I	5

* Annex A is part of the Agreement.
** The here above product list classification is based on the classification claim of the manufacturer and under its sole responsibility (MDD 93/42/EEC, article 2 & Annex IX; MEDDEV 2.4/1 Rev.9, chapter 3.1 & 3.3)

Manufacturer's Name	Obelis S.A.	BECI
[redacted]		
Signature:	Signature: P.O.	Signature:
Date: 18/4/16	Date: 25/05/16	Date:
Stamp:	Stamp:	Stamp:

BIOMAX RUBBER INDUSTRIES SDN. BHD. 893311-W

Obelis s.a.
Registered Address :
Bld Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

S. FERRETTI
C.C.O.

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
Becl
26 -05- 2016
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

OBELIS s.a. Anti-Counterfeiting Label