



CERTIFICATE



This is to certify that

[REDACTED]
[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



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



CHAMBRE DE COMMERCE
ET D'INDUSTRIE DE
BRUXELLES
KAMER VAN
HANDEL EN
NIJVERHEID VAN
BRUSSEL



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



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: ██████████ SDN BHD

ADDRESS: LOT ██████████ ██████████ 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
Brussels, the

26 MAI 2016

P.O.

Mr. G. Elkayam CEO
Obelis sa

date & stamp

S. FERRETTI
C.C.O.

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

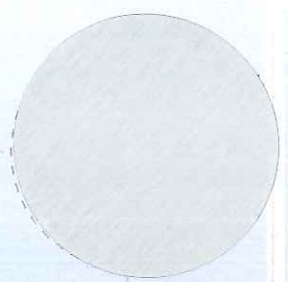
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

Brussels Enterprise
Commerce & Industry

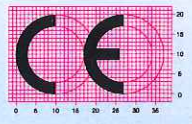
date & stamp



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.



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

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

Signature: _____

Signature: P.O. _____

Signature: _____

Date: _____

Date: 25/05/16

Date: _____

Stamp: _____

Stamp: _____

Stamp: _____



Obelis s.a.
Registered Address:
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S. FERRETTI
C.C.O.



OBELIS s.a. Anti-Counterfeiting Label

