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

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 SA
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: BIOMAX RUBBER INDUSTRIES SDN BHD

ADDRESS: LOT 3612, OFF JALAN KUALA SELANGOR, BATU 19, MUKIM DARUL SG BULOH, 47000 SUNGAI BULOH, 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

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

Brussels, the 26 MAI 2016

Brussels Enterprise
Commerce & Industry
date & stamp

Nastasja OTTE

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

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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
Biomax Rubber Industries S/B		
Signature:	Signature:	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.

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OBELIS s.a. Anti-Counterfeiting Label