



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

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

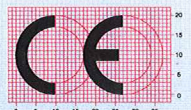
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

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.



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

Biomax Rubber Industries s/b

Obelis S.A.

BECI

Signature: _____

[Handwritten Signature]

Signature: _____

[Handwritten Signature]

Signature: _____

Date: _____

18/4/16

Date: _____

25/05/16

Date: _____

Stamp: _____

Stamp: _____

Stamp: _____



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S. FERRETTI
 C.C.O.

