



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 hereabove 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. CE-REP
 Registered address :
 Bd Général Wahis 53
 1030 Bruxelles
 Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

G. Elkayam
 Mr. G. Elkayam CEO
 Obelis sa

date & stamp



*Brussels Enterprise
 Commerce & Industry*

date & stamp

OBELIS
 by the Brussels Chamber of Commerce
 and Industry
 17 DEC. 2013
 Brussels, the

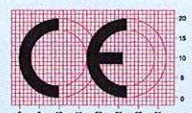


Obelis European Authorized Representative Center is a member of the European Association of Authorized Representatives (E.A.A.R.), ISO 9001 : 2008 and ISO 13485 : 2003 certified in accordance to the profession of a European Authorized Representative.

*also applicable to Class I s & m

** and provided that the product classification will not be rejected by the competent authorities

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Annex A – List of devices

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

No.	Device type	Commercial name	Class*	Rule	Catalogue reference number	Short description and intended use
1	Examination Gloves	Natural Rubber Latex Examination Gloves (Powdered)	1	5	G001	Medical examination. To prevent contamination between patient and examiner
2	Examination Gloves	Natural Rubber Latex Examination Gloves (Powder Free)	1	5	G001	Medical examination. To prevent contamination between patient and examiner
3	Examination Gloves	Nitrile Examination Gloves (Powdered)	1	5	G002	Medical examination. To prevent contamination between patient and examiner
4	Examination Gloves	Nitrile Examination Gloves (Powder Free)	1	5	G002	Medical examination. To prevent contamination between patient and examiner

The above product identification is based on the classification class of the manufacturer and under its sole responsibility (1990/53/EEC, article 3 & Annex IX, MEDDEV 2.4/1 Rev.9, number 21 & 22)

Manufacturer's Name

Obelis S.A.

BECI

~~AKG INDUSTRIES S/B~~

Signature:

Signature:

Signature:

Date:

Date:

Date:

Stamp:

Stamp:

Stamp:

CHAMBRE DE COMMERCE
 ET D'INDUSTRIE DE
 BRUXELLES



17-12-2013

KAMER VOOR HANDEL EN
 NIJVERHEID VAN BRUSSEL



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