obelis SA
EUROPEAN AUTHORIZED REPRESENTATIVE CENTER

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. - O.E.A.R.C.
Registered address :
Bd Général Wahis 53
1030 Bruxelles
Tél. +32 2 732 59 54 - Fax +32 2 732 60 03

Mr. G. Elkayam CEO
Obelis sa
date & stamp

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
17-12-2013
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

Brussels Enterprise
Commerce & Industry
date & stamp

SEEN by the Brussels Chamber of Commerce
Elke Teck
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

Registered Address: Bd. Général Wahis 53 - 1030 Brussels I Registered Office Address: Av. de Tervueren 34 B44 - 1040 Brussels - Belgium
T: + 32 (0) 2 732 5954 I F: + 32 (0) 2 732 6003 I Email: mail@obelis.net I Website: www.obelis.net

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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 here above product list classification is based on the classification class of the manufacturer and under its sole responsibility (IIDD 93/42/EEC, article 2 & Annex IX, MEDDEV 2.4/1 Rev.9, chapter 3.1 & 3.4)

Manufacturer's Name	Obelis S.A.	BECI
AYG INDUSTRIES SDN BHD	G.ELKAYAM C.E.O.	CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
Signature:	Signature:	Signature:
Date: 14/9/13	Date: 13/12/2013	Date: 17 -12- 2013
Stamp: AYG INDUSTRIES SDN BHD * 927814W *	Stamp: OBELIS s.a. - O.E.A.R.C Registered address : Bd Général Wahis 53 1030 Bruxelles Tél. +32 2 732 59 54 - Fax +32 2 732 60 03	Stamp: KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL