Obelis SA
European Authorized Representative Center

CERTIFICATE OF CE (IVD) NOTIFICATION

Ref. No.: JW 0625-2012

Order No.: FM 0568-2012

Date: 26/07/2012

THIS IS TO CERTIFY THAT, ACCORDING TO THE EUROPEAN COUNCIL DIRECTIVE 98/79/EC, OBELIS S.A. (O.E.A.R.C.) PERFORMED ALL NOTIFICATION DUTIES AND RESPONSIBILITIES AS THE EUROPEAN AUTHORIZED REPRESENTATIVE (EC REP) OF:

NAME: ROBONIK (INDIA) PVT. LTD.

ADDRESS: PLOT NO. A-374. TTC, MIDC INDUSTRIAL AREA,
DIST. THANE,
MAHAPE, NAVI MUMBAI-400 710, INDIA.

AS STIPULATED AND DEMANDED BY THE AFOREMENTIONED DIRECTIVE.

The Manufacturer declares that the IVD 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 according to the 98/79/EC Directive – article 10 requirements including the EC Declaration of Conformity confirming that his In-Vitro Diagnostics medical devices, as stipulated here above, are fulfilling the applicable requirements of the European Council Directive 98/79/EC

The notification of the following In-Vitro Diagnostic medical device(s) has been completed by Obelis s.a. (O.E.A.R.C.) on the 22/12/2009 in compliance with the European Council Directive 98/79/EC - article 10 requirements.

IN-VITRO DIAGNOSTIC MEDICAL DEVICES: PLEASE SEE ANNEX A - LIST OF DEVICES (1 PAGE, 2 DEVICES)

As of the 23/12/2009, and as long as the manufacturer will continue complying with the here above mentioned requirements* he therefore:

- Is required to affix the CE marking on these devices;

- place these devices in the Territory of Belgium and the other EEA Member States (excluding territories not in alignment with Decision 2010/227/EU).

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
23-08-2012
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

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

G. Elkayam CEO

Mr. G. Elkayam CEO
Obelis sa
date & stamp

SEEN
by the Brussels Chamber of Commerce

Brussels, the 23-08-2012

ELKE TECK

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.) and ISO 9001-2008 certified in accordance to the profession of a European Authorized Representative.

*and provided that the product classification will not be rejected by the Competent Authorities.

Corporate Offices Bd. Général Wahis 53 - 1030 Brussels I Registered Office 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

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Annex A* - List of Devices

(Recital 29 of the Directive 98/79/EC on In Vitro Diagnostic Medical Devices)

No.	Generic Device Term	Commercial name	Class**	Catalogue reference number	Short description and intended use	GMDN/EDMS code***
1	ELISA PLATE ANALYSER	READWELL TOUCH	OTHER DEVICE (except Annex II and self-testing devices)	User Manual –Readwell Touch	Micro plate analyzer it measure and interpret enzyme immunoassay results. Intended for In Vitro Diagnostic use only.	30839
2	ELISA PLATE WASHER	WASHWELL PLATE	OTHER DEVICE (except Annex II and self-testing devices)	User Manual –Washwell Plate	Micro plate Washer is an accessory for Elisa Plate Analyser it wash the enzymatic microplates and is intended for In Vitro Diagnostic use only.	30839

* 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 (IVD 98/79/EC).
*** GMDN or EDMS codes are mandatory information to complete the Notification.

EUROPEAN AUTHORIZED REPRESENTATIVE CENTRE
Obelis SA
SINCE 1988

Manufacturer's Name	***Obelis S.A.***	***BECI***
Subhash Punja.		
Signature:	***Signature:*** G.ELKAYAM C.E.O.	***Signature:***
Date: 06/07/2012	***Date:*** 23/8/2012	***Date:***
Stamp: ROBONIK (INDIA) PVT. LTD.	***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:*** CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES 23-08-2012 KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

OBELIS s.a. Anti-Counterfeiting Label