Obelis SA
European Authorized Representative Center

CERTIFICATE OF CE (IVD) NOTIFICATION

Ref. No.: AM 1603-2013

Order No.: IO 2393-2013

Date: 13/11/2013

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 07/11/2013 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 (2 PAGES, 5 DEVICES)

As of the 08/11/2013, 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;

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

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Elke Teck 14 NOV. 2013

G.ELKAYAM C.E.O.

Mr. G. Elkayam CEO
Obelis sa
date & stamp 13/11/2013

CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
14 -11- 2013
Brussels Enterprise Commerce & Industry
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

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.

Obelis s.a. - O.E.A.R.C.
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1030 Bruxelles
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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	Biochemistry Analyser	Prietest easylab	Other Device (Except Annex II and Self Testing Devices)	User Manual – prietest easylab	prietest easylab, is a pre programmed Biochemistry analyzer. It measures the optical densities of samples and it uses algorithm to calculate results, which are used for biochemical investigations. It has direct access to stored programs. It is intended for in vitro diagnostic use , and should be used by Qualified and healthcare professionals, only.	56679
2	Coagulation Analyser	FOURCLOT	Other Device (Except Annex II and Self Testing Devices)	User Manual – FOURCLOT	FOURCLOT ,is a programmable Coagulometer with a sophisticated on board software and user-friendly touch screen. Its versatile and unique software supports most of the calculation required for interpretation of results. It is a reliable, high precision machine. It has a user-friendly program and capacity of storing the programmed analytical methods and the QC results. It is intended for in vitro diagnostic use , and should be used by Qualified and healthcare professionals, only.	56689
3	Urine Chemistry Analyser	URICHA	Other Device (Except Annex II and Self Testing Devices)	User Manual – URICHA	URICHA is a reflection photometer for the analysis of urine test sticks. The measurements are performed under standardized conditions; measured value will display, printed and can be transferred to a computer. URICHA is designed for in-vitro diagnostic use(IVD) and should be used by Qualified and healthcare professionals, only.	30852
4	ELISA Plate Shaker-Incubator	lisa-SHAKE	Other Device (Except Annex II and Self Testing Devices)	User Manual – lisa-SHAKE	lisa-SHAKE instrument is intended for ELISA applications, with superior temperature control and efficient orbital shaking, it efficiently increases the sensitivity and specificity	43860

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Rejected as IVD

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					of ELISA assays and reduces incubation times, providing high performance and productivity meeting even the highest assay needs of any universal ELISA assays. A high performance temperature controlled shaker which accommodates up to 2 **ELISA assay plates. Temperature, shaking speed and incubation time are fully programmable via keypad, while status parameters are displayed on the LCD in real-time.**	
5	**Fully Automatic Random Access Biochemistry Analyser**	**AUTORA**	**Other Device (Except Annex II and Self Testing Devices)**	**User Manual – AUTORA**	**AUTORA is a user programmable, Fully Automatic Random Access Biochemistry Analyser . It measures the optical densities of samples and it uses algorithm to calculate results, which are in turn used for biochemical investigation. It has a Photometer operating in visible & UV range. Large Semiconductor memory is used for storing reagent programs, QC results and patient data results. Desktop PC with windows 7 operating system is connected to instrument with USB connection . Standard IBM compatible Keyboard and Mouse is used for interferface. It is intended for in vitro diagnostic use ,** and should be used by Qualified and healthcare professionals, only.	**56678**

* 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.

Manufacturer's Name ***Robonik (India) Pvt. Ltd.***

Signature: _____

Date: ***26-08-2013***

Stamp:

ROBONIK (INDIA) PVT. LTD.

Obelis S.A.

Signature: G. ELAYAM C.E.O

Date: 13/11/2013

Stamp:

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Registered Address :
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1030 Bruxelles
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BECI

Signature: _____

Date: 14-11-2013

Stamp:

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