



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 Diagnostic 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 to the extent of the agreement with Decision 2010/227/EU).



GELKAYAM
C.E.O.

Mr. G. Elkayam CEO
Obelis sa

date & stamp 13/11/2013



BEEN
Elke Teck
NOV. 2013



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.
Registered Address:
1030 Brussels - Belgium
Tel: +32 (0) 2 732 59 54 - Fax: +32 (0) 2 732 60 03

Corporate Offices Bd. General Wafis 53 - 1030 Brussels | Registered Office Av. de Tervueren 34 B44 - 1040 Brussels - Belgium
T: + 32 (0) 2 732 5954 | F: + 32 (0) 2 732 6003 | Email: mail@obelis.net





NOTARISED

Rajani Pathak
B.Sc., LL.M.
NOTARY



1st Floor, Vision Business Centre,
Bhwardiwala Terrace, Adjacent the Court,
Thane. Ph.: 25340395, 9821138766

NOTED & REGISTERED
Sr. No. E 9624 | 17

19 JUL 2017



The Signature of Shri.....
..... is hereby certified.
Home Department, Maharashtra accepts
no responsibility for the contents
of the document.



[Signature]

Section Officer
Home Department
Government of Maharashtra
Mantiralya, Mumbai

19 JUL 2017



MR. SUKHADEO DADU CHAVAN
ASSISTANT MANAGER

A copy of this document / CERTIFICATE
has been recorded with the Chamber

[Signature]

Authorised Signatory
Bombay Chamber of Commerce and Industry
Regn. No. 47533... Date 9 JUL 2017

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	43880



Becl
CHAMBRE DE COMMERCE ET D'INDUSTRIE DE BRUXELLES
14-11-2013
KAMER VOOR HANDEL EN NIJVERHEID VAN BRUSSEL

Referred as IVD

FERRETTI C.C.O.

				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	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.

Obelis S.A.

BECI

Signature: _____

Signature: _____

Date: 26-08-2013

Date: 13/11/2013

Stamp:



Stamp:



Obelis s.a. - O.E.A.R.C.

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