Obelis SA
European Authorized Representative Center

CERTIFICATE OF CE (IVD) NOTIFICATION

Ref. No.: AF 4210-2015

Order No.: AF 4071-2015

BELGIUM

Date: 07/08/2015

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: A-374, TTC, MIDC, INDUSTRIAL AREA, MAHAPE, NAVI MUMBAI, 400-710, INDIA

SEEN by the Brussels Chamber of Commerce
Brussels, the 07 AOUT 2015

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 devices has been completed by Obelis s.a. (O.E.A.R.C.) on the 04/08/2015 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, 3 DEVICES)

As of the 05/08/2015, 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).

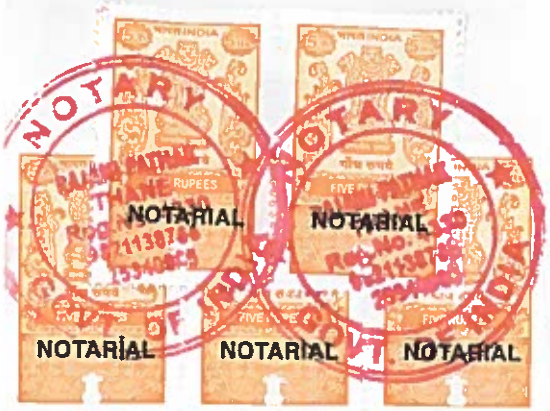
Mr. G. Elkaram, CEO
Obelis sa
date & stamp

Brussels Enterprise
Commerce & Industry
date & stamp

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

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.

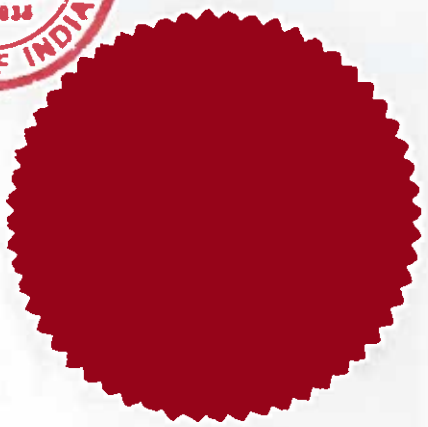
*and provided that the product classification will not be rejected by the Competent Authorities.



NOTARISED

Rajani Pathak
B.Sc., LL.M.
NOTARY
1st Floor, Vision Business Centre,
Shiwandiwala Terrace, Adjacent the Court,
Thane. Ph.: 25340395, 9821138766

NOTED & REGISTERED
Sr. No. E 9619/17
19 JUL 2017



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

Section Officer
Home Department
Government of Maharashtra
Mantralaya, Mumbai

19 JUL 2017

MR. SUKHADEO DADU CHAVAN
ASSISTANT MANAGER

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

Authorised Signatory
Bombay Chamber of Commerce and Industry
Regn. No. 4535 Date 19 JUL 2017

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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 SMART**	**Other Device (Except Annex II and Self Testing Devices)**	**User Manual –prietest SMART**	**prietest SMART – Windows based system , with Intuitive, sophisticated software for easy operation, Large and colourful display makes operation more trouble free. It is a programmable Biochemistry Analyzer with a user-friendly touch screen. It measures the optical densities of samples and it uses algorithm to calculate results, which are used for biochemical investigation. It is a photometer operating in the UV visible range. The instrument is an open photometer suitable for absorbance (optical density) measurement as well as sample concentration determination. It has a user-friendly program and capacity of storing the programmed analytical methods, Test Results and the QC results. It is intended for in vitro diagnostic use.**	**56679**
2	**Biochemistry Analyser**	**prietest COMPACT**	**Other Device (Except Annex II and Self Testing Devices)**	**User Manual –prietest COMPACT**	***prietest COMPACT* - is a programmable Biochemistry Analyzer with a Keypad. It measures the optical densities of samples and it uses algorithm to calculate results, which are used for biochemical investigation. It is a photometer operating in the visible range. The instrument is an open photometer suitable for absorbance (optical density) measures as well as sample concentration determination. 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.**	**56679**
3	**Automatic ELISA PLATE WASHER**	**Washwell PLATE PLUS**	**Other Device (Except Annex II and Self Testing Devices)**	**User Manual –washwell PLATE PLUS**	***Washwell Plate PLUS* - It is an accessory for ELISA Plate Analyser, it wash the enzymatic microplates as specified by reagent manufacturer. while performing all ELISA tests. It is intended for in vitro diagnostic use.**	**17489**

* 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: 20-04-2015

Stamp:

ROBONIK (INDIA) PVT. LTD.

Obelis S.A.

Signature: G. ELKAYAM C.E.O.

Date: 7/8/2015

Stamp:

BECI

Signature:

Date:

Stamp:

BOMBAY CHAMBER OF COMMERCE AND INDUSTRY ★1836★

OBELIS s.a. Anti-Counterfeiting Label

OBELIS s.a. - O.E.A.R.C
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1030 Bruxelles