Obelis SA
European Authorized Representative Center

CERTIFICATE OF CE (IVD) NOTIFICATION

Ref. No.: FM 0447-2012

Order No.: FM 0429-2012

Date: 30/05/2012

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 device(s) comply(ies) 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 23/12/2009 *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, 1 DEVICE)

As of the 24/12/2009, 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).

SEEN
by the Brussels Chamber of Commerce
Evelien Jonckheere

G. EL KAYAM
C.E.O.

Mr. G. Elkayam CEO
Obelis sa
date & stamp
31/5/2012

Brussels Enterprises, the Commerce & Industry
date & stamp
06 JUIN 2012

Obelis s.a. - O.E.A.R.C.
Registered Address:
Bd. Général Wahis 53
B-1030 Bruxelles
Tel. +32 2 732 5954 - 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,
Shivandiwala Terrace, Adjacent the Court,
Thane. Ph.: 25340395, 9821138766

NOTED & REGISTERED
Sr. No. E 9618/17

19 JUL 2017

MR. SUKHADEO DADU CHAVAN
ASSISTANT MANAGER

MR. SUKHADEO DADU CHAVAN
ASSISTANT MANAGER

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

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

Authorised Signatory
Bombay Chamber of Commerce and Industry
Regn. No. 47536 Date

19 JUL 2017

Ref. No.: FM 0429-2012

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 Touch**	**Other Device (Except Annex II and self testing devices)**	**User Manual – Prietest Touch**	**Prietest TOUCH , is intended to be used in laboratory, pathology and blood banks. It measures the optical density of the sample to process the results, which are further use in biochemical investigation . It displays the results as well as generate the report . It analyses the biochemical such as Substrates, Serum Serum Proteins, Enzymes, Drug levels etc. from the body fluids such as Serum, Plasma. It is useful in diagnosis of clinical diseases .**	**GMDN code 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 SINCE 1988 Obelis SA

Manufacturer's Name	***Obelis S.A.***	***BECI***
ROBONIK (INDIA) PVT. LTD.		
Signature: _____	***Signature:*** _____	***Signature:*** _____
Date: 17/05/12	***Date:*** 31/5/2012	***Date:*** _____
Stamp: ROBONIK (INDIA) PVT. LTD.	***Stamp:*** Obelis S.A. - O.E.A.R. Registered Address: Bld Général Wahis 53 1030 Bruxelles Tél. +32 2 732 59 54 - Fax +32 2 732 60 03	***Stamp:***

BOMBAY CHAMBER OF COMMERCE AND INDUSTRY ★ 1836 ★ BOMBAY CHAMBER

OBELIS s.a. Anti-Counterfeiting Label