

## EC Declaration of Conformity



The undersigned **ROBONIK (INDIA) PVT. LTD.**, having its factory in Plot No. A-374, TTC, MIDC Industrial Area, Mahape, Navi Mumbai - 400 710, INDIA. Tel.: +91-(22)-67829700, Fax: +91-(22)-67829701, manufacturer of diagnostic devices, with Company Quality Management System in compliance with standards ISO 9001 and ISO 13485.

Declares that the devices listed in the annex to this declaration, comply with all the essential requirements listed in Annex I of Directive 98/79/EC and obligations specified in Annex III, art. 2-5 of Directive 98/79/EC for In vitro Medical Diagnostic Devices.

Therefore **ROBONIK (INDIA) PVT. LTD.** declares and assures the following :

1. The Devices Listed in the annex to this declaration comply with the applicable provisions of IVD Directive 98/79/EC.

**MR. SUKHADEO DADU CHAVAN**  
ASSISTANT MANAGER

2. The devices listed in the annex to this declaration is not included in the list A and B of the Annex II of IVD Directive 98/79/EC

Date of issue : 1<sup>st</sup>, June 2015



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

  
Authorized Signatory  
Bombay Chamber of Commerce and Industry  
Regn. No. 47538

Date 19 JUL 2017

Place :

Navi Mumbai

Signature





Name of Authorized Signatory : **Mr. Subhas Punja**

Position Held in Company : **Director**

### **ROBONIK (INDIA) PVT. LTD.**

Plot No.: A-374, TTC, MIDC Industrial Area, Mahape, Navi Mumbai - 400 710

• Tel.: +91 (22) 67829700 • Fax : +91 (22) 67829701 • E-mail : sales@robonikindia.com • Website : www.robonik.in



NOTARISED

*R*  
**Rajani Pathak**  
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NOTARY

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*MN*

**NOTED & REGISTERED**

Sr. No. E 9625/17

9 JUL 2017



Tổng Lãnh sự quán nước CHXHCN Việt Nam tại Mumbai, Ấn Độ  
Consulate General of the S.R. of Vietnam in Mumbai, India

CHỨNG NHẬN / HỢP PHÁP HÓA LÃNH SỰ  
CONSULAR AUTHENTICATION

1. Quốc gia / Country: VIỆT NAM

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CHÍNH QUYỀN BANG MAHARASHTRA

được chứng nhận / hợp pháp hóa lãnh sự  
Certified

5. tại MUMBAI 6. ngày 24/07/2017

7. Cơ quan cấp TL.SQ VIỆT NAM TẠI MUMBAI, ẤN ĐỘ

8. Số 695/HPH/2017

Ký tên và đóng dấu / Signature and seal/stamp  
TL. Tổng Lãnh sự Lãnh sự



Từ Văn Phúc

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



*[Signature]*  
Section Officer  
Home Department  
Government of Maharashtra  
Mumbai

19 JUL 2017

### Annex to the Declaration

1	Biochemistry Analyser - prietest TOUCH
2	Biochemistry Analyser - prietest SMART
3	Fully Automated Random Access Biochemistry Analyser - AUTORA
4	Elisa Plate Analyser - readwell TOUCH
5	Elisa Plate Washer - washwell PLATE
6	Four Channel Coagulation Analyser - four CLOT
7	Activated Clot Time Machine - eazy CLOT

ROBONIK



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