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**Central Drugs Standard Control Organization**  
**Directorate General of Health Services**  
**Ministry of Health & Family Welfare**  
**(Medical Devices & Diagnostics Division)**

Food & Drugs Administration Bhawan,  
Kotla Road, New Delhi-110002

File No. 29/Misc/3/2017-DC (314)

Date: 9 DEC 2017

To ✓

M/s . InKosBio Pharma,  
R-775, 2 Floor, New Rajendra Nagar ,  
New Delhi-110060.

**Sub: - Clarification for the import of Electro Impedance Mammograph**

Sir,

Please refer to your application no nil dated 09.11.2017 received by this office vide diary no 29455 dated 14.11.2017 on the subject matter

The case has been examined in the light of documents submitted by you. In this connection, it is stated that the proposed products "Electro Impedance Mammograph under the models MEM 20-11 and MEM 20-08" intended for imaging and diagnostics of pathological changes of the breast tissues is not notified as Medical Device under section 3 b(iv) of Drugs & Cosmetics Act thereunder.

Yours faithfully,



(Dr. V. G. Somani)  
Joint Drugs Controller (I)

TELEPHONE : 91-22-2599 0100 / 0101  
फैक्स / FAX : 91-22-2599 0650, 2558 3230  
वेबसाइट / WEBSITE : www.aerb.gov.in



नियामक भवन / NIYAMAK BHAVAN,  
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भारत सरकार  
GOVERNMENT OF INDIA  
परमाणु ऊर्जा नियामक परिषद  
ATOMIC ENERGY REGULATORY BOARD

RADIOLOGICAL SAFETY DIVISION

Dr. G. Sahani  
Head, MRAS

Tel: 022-25990653

Fax: 022-25990650

Email: [gsahani@aerb.gov.in](mailto:gsahani@aerb.gov.in)

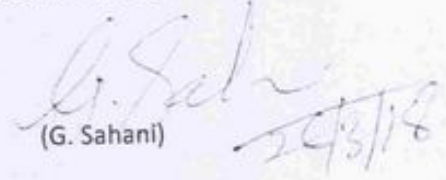
March 26, 2018

Ref. No. AERB/RSD/DRX/Gen/2018/ 564

Dear Sir,

This is in reference to your letter received by AERB on March 23, 2018 regarding clarification on import of non-invasive medical device "MEM (Multi frequency Electrical Impedance Mammography)".

In this connection, on scrutiny of the information provided by you along with afore mentioned letter we understand that above medical device "MEM (Multi frequency Electrical Impedance Mammograph)" neither generates ionizing radiation nor uses radioactive source. Hence, the said equipment does not come under the purview of AERB.

  
(G. Sahani)

Mr. Viacheslav Petrakov,  
Director,  
InKosBio Pharma,  
R-775, 2 floor,  
New Rajendra Nagar,  
New Delhi-110060

## InKosBio Pharma

R-775, 2 floor,  
New Rajendra Nagar  
New Delhi, 110060  
tel: +91 11 49126591  
m: +91 9811372045

e-mail [info@inkosbio.com](mailto:info@inkosbio.com)  
Web: [www.inkosbio.com](http://www.inkosbio.com)

The Drugs Controller General (India)

Directorate General of Health Service,

FDA, Bhawan, Kotla, Road

New Delhi-110002

**MEDICAL DEVICE**



**InKosBio**  
PHARMA

Date: 09/11/2017



**Subject: Application for Clarification below specified Product to import into India.**

Dear Sir,

We are hereby submitting our application for import Clarification in respect of the below mentioned medical device.

- **Electro Impedance Mammograph**
  - a. MEM 20-11
  - b. MEM 20-08

- **Description:**

The device is intended for imaging and diagnostics of pathological changes of the breast tissues.

- **Principle of the device operation**

Various organs and tissues in a human body possess different electrical properties. For instance, it is a well-known fact that many tumours, in particular malignant breast tumours, feature electrical conductivity (ability to conduct electrical current), which differs considerably from the electrical conductivity of surrounding healthy tissues. The MEM makes it possible to obtain the picture of biological tissues electrical conductivity distribution in the breast in its transverse sections and locate such tumours in the obtained images.

- **Technical features:**

The device comprises a measuring block with a built-in microprocessor control system, which houses a matrix with 256 electrodes.

Two remote electrodes, which are positioned on a patient's arm, are connected via a cable to the measuring block.