

CERTIFICATE NO:
DIPP231083



Government of India
Ministry of Commerce & Industry
Department for Promotion of Industry and Internal Trade



CERTIFICATE OF RECOGNITION

*This is to certify that **RAAMAH BIO CARE PRIVATE LIMITED** incorporated as a **Private Limited Company** on **08-04-2023**, is recognized as a startup by the **Department for Promotion of Industry and Internal Trade**. The startup is working in **'Healthcare & Lifesciences' Industry** and **'Medical Devices Biomedical'** sector as self-certified by them.*

This certificate shall only be valid for the Entity up to **Ten** years from the date of its incorporation
only if its turnover for any of the financial years has not extended **₹ 100 Cr.**

25-11-2025

DATE OF ISSUE

07-04-2033

VALID UPTO



No.29/Misc./03/2020-DC (228)
Government of India
Directorate General of Health Services
Central Drugs Standard Control Organisation
(Medical Device Division)

FDA Bhawan, Kotla Road,
New Delhi-110002.

Dated: 11 FEB 2021

To,

M/s. Ramah Biosolutions Pvt. Ltd.,
Ground Floor, G-15, Rajinigandha Apartments,
ChaitanyaPuri, Hyderabad-50060.

Sub: - NOC for oral cancer screening device (Dr Oroscope) under the MDR-2017- Regd.

Sir,

Please refer to your email dated 29.01.2021 by this office vide P-2065010 dated 05.02.2021 regarding the above mentioned subject.

The case has been examined in the light of documents submitted by you. In this connection, it is stated that the products viz., Dr. Oroscope intended for diagnose of pre-cancerous and cancerous conditions without a biopsy and also used as a follow-up aid during the post-recovery period to identify recurrences in conditions of cancer is currently not under licensing as per Drugs and Cosmetics Act and Medical Device Rules, 2017 thereunder. However, as per the S.O. 648(E) dated 11.02.2020 the proposed product falls under the definition of Medical Device.

In view of above, you can voluntarily register the product as per notification vide G.S.R. 102 (E) dated 11.02.2020 on portal established by CDSCO.

Yours faithfully,


(Dr. Ravi Kant Sharma)
Deputy Drugs Controller (I)

RAMAH BIO SOLUTIONS PRIVATE LIMITED

H.No. 18-97, G-15, Rajanigandha Apartments, Gaddiannaram, Saroor Nagar, Chaitanyaepuram, Hyderabad, R.R.Dist, Telangana, India, Pin 500060



Date: 6-3-2020

Dear sir,

Sub : - Request for NOC with ref Video conference in March

We at Ramah Biosolutions Pvt. Ltd., Hyderabad thank you for the video conferencing on March 6th 2019. Indeed, it was a great honor for us to interact with the Drug Controller General of India, the deputy Drug Controller and the rest of the team.

Further to our interaction, since our device does not fall under any category of the regulation, we requested the screening committee to help us with a formal No Objection Certificate (NOC) or anything equivalent for us go for commercialization of our product "Dr. Oroscope", as many of our potential clients which also include the state governments, have asked for. Upon our request, respected DCGI has asked us to write the same and share the photos and documents taken with the device for the committee to do the necessary.

Please find attached word document of introduction to the device alongside with a comparative chart of current devices available in the worldwide market, PDF of a publication about the product, the photos taken with the device and the ethical committee letter given by the MNJ Institute of Oncology to validate the device. Kindly do the needful.

We again thank DCGI CDSCO for initiating a novel way to interact with start ups and this initiative of yours would go a long way and fetch dividends to encourage the healthcare innovation in our country.
Thank you.

Regards
Dr D Rama Raju,
9949094449

ETHICAL COMMITTEE APPROVAL (MNJ)



INSTITUTIONAL ETHICS COMMITTEE M N J INSTITUTE OF ONCOLOGY & REGIONAL CANCER CENTER



Redhills, Hyderabad - 500 004, Telangana.

+91(40)23318414/22/24, 23397000 Fax : +91 (40) 23314063

E-mail : mnjethicscommitte@gmail.com

Institutional Ethics Committee
(Regd No: ECR/227/Inst/AP/2013/RR-16.)

LETTER OF APPROVAL / REJECTION

Date: 20th-Dec-2017.

Study Title: "Evaluation of Efficacy of non invasive Oral cancer screening device."-----
Dr. Rama Raju.

The Institutional Ethics Committee, MNJ Institute of Oncology & Regional Cancer center, Hyderabad reviewed and discussed the documents submitted by you regarding "Evaluation of Efficacy of non invasive Oral cancer screening device."

The Following Documents were reviewed -

- Study Protocol
- Informed Consent Forms

A Prospective Study in its meeting held on 16th Dec 2017 at MNJ Institute of Oncology & Regional Cancer Centre.

The following members of the Ethics Committee were present at the meeting held on 16th Dec 2017, 11:00 AM at MNJ Institute of Oncology and Regional Cancer Centre, Red Hills, Hyderabad-500004, T.S,

Name	Qualification	Designation/ Title	Affiliations as to the Institution Yes/No
Dr.G.Sham Sunder	M.S,FRCS,DGO	Chairman	No
Dr. M. Muralidhar	Asst.Prof.Surgical Oncology	Member Secretary	Yes
Dr. Priya Kumari	M. Sc, Ph. D	Lay Person	No
Mrs. Vimala Badruka	MSW	Social Worker	No

Page 1 of 2

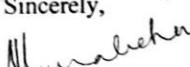
Smt. Lakshmi Sailaja	D. Pharma	Pharmacist	Yes
Dr. N.Jayalatha	MD	Member	Yes
Dr. Gayatri Palat	Assoc. Prof. of Palliative Care	Member	No
Sri. Kotha Krishna Reddy	LLB	Advocate	No
Dr. Vijaya Kumari	MD	Member	No
Dr. Ch.N.Raj kumari	MD	Member	No
Dr.Ramesh maturi	Asst.Prof. Surgical Oncology	Member	Yes
Dr.Raghuraman	Asst.Prof.Radiotherapy	Member	Yes
Dr.K. Swetha	M.D,Bio Chemistry	Basic Medical Scientist	Yes

The Ethics Committee has approved the trial to be conducted in its presented form.

The Institutional Ethics Committee, MNJ Institute of Oncology & Regional Cancer Centre, Hyderabad expects to be informed about the progress of the study, any SAE occurring in the course of the study, any changes in the protocol and patient information/informed consent and asks to be provided a copy of the final report.

We hereby confirm that the Institutional Ethics Committee, MNJ Institute of Oncology & Regional Cancer Centre, Hyderabad is organized and operates as per GCP and applicable regulations.

Yours Sincerely,


 (Dr. M. Muralidhar)
 Member Secretary,
 MNJ Institutional Ethics Committee.

Secretary
 Ethics Committee
 MNJ Institute of Oncology & RCC
 Red Hills, Hyderabad

SAVITHA ETHICAL COMMITTEE APPROVAL (PhD)

Research Title	Efficacy and validation of Autofluorescence visualization technique as a diagnostic and prognostic marker in Oral Potentially Malignant disorders - A Prospective clinical study.
Research Question	Is Autofluorescence visualization technique efficacious in diagnosis and prognosis of Oral Potentially Malignant disorders?
Objectives	To evaluate the efficacy of Autofluorescence visualization technique in the diagnosis and prognosis of Oral Potentially Malignant disorders.
Alternative hypothesis H_1	-To evaluate the efficacy of Autofluorescence visualization technique through Velscope in the diagnosis and prognosis of Oral Potentially Malignant disorders -To evaluate the efficacy of Autofluorescence visualization technique by Dronoscope in the diagnosis and prognosis of Oral potentially Malignant disorders -Compare the efficacy of the technique with Toluidine blue staining -To evaluate the efficacy of Autofluorescence visualization technique in the progression and follow up of Oral potentially Malignant disorders
Null hypothesis H_0	Autofluorescence visualization technique is not efficacious in the diagnosis and prognosis of Oral potentially Malignant disorders.

ETHICAL COMMITTEE CLEARANCE FROM SVS INSTITUTE OF DENTAL SCIENCES

SVS INSTITUTE OF DENTAL SCIENCES

INSTITUTIONAL ETHICS COMMITTEE

DECISION FORM

Name: Dr.D.RAMARAJU

Contact Address:
H.NO: 3-1-511, road no.5, Nvodaya Colony, L.B.Nagar, Hyderabad,
Telangana-74.

Phone Number 9949094449

Title of the Dissertation:

Evaluation of efficacy of non invasive Oral cancer screening device

**Is this a "New" or
"Continuing" Project**

New project

Date of Submission: 5/12/2017

**Date of Resubmission
(if applicable):**

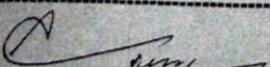
SVSIDS /OMR /4)2017

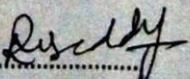
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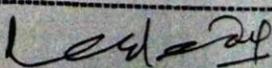
IEC decision: 9

Approved
 Not Approved

Comments:


IEC Chairman


IEC Secretary


Principal



क्रम सं/ Serial No. : 153275



पेटेंट कार्यालय, भारत सरकार The Patent Office, Government Of India

The Patent Office, Government Of India
Certificate of Registration of Design

डिजाइन सं. / Design No

394910-001

तारीख / Date

12/09/2023

पारस्परिकता तारीख / Reciprocity Date

देश / Country: भारत ग्रंथालय एवं अधिकारी, दुर्लिङमानो नसा विवाहान, भारत सरकार, वौद्धिक संपदा कार्यालय, भारत सरकार, Intellectual Property India, वौद्धिक संपदा कार्यालय, भारत सरकार, वौद्धिक संपदा दफतर, भारत सरकार, वौद्धिक संपदा कार्यालय, भारत सरकार, वौद्धिक

प्रमाणित किया जाता है कि संलग्न प्रति में वर्णित डिजाइन जो *PORTABLE INTRA ORAL CANCER SCREENING DEVICE* से संबंधित है, का पंजीकरण, श्रेणी 24-02 में 1. Dr D. Rama Raju 2. D. Advaith Sai Raju 3. D. Harshitha के नाम में उपर्युक्त संख्या और तारीख में कर लिया गया है।

Certified that the design of which a copy is annexed hereto has been registered as of the number and date given above in class 24-02 in respect of the application of such design to *PORTABLE INTRA ORAL CANCER SCREENING DEVICE* in the name of 1. Dr D. Rama Raju 2. D. Advaith Sai Raju 3.D. Harshitha.

डिजाइन अधिनियम, 2000 तथा डिजाइन नियम, 2001 के अध्यधीन प्रावधानों के अनुसरण में

In pursuance of and subject to the provisions of the Designs Act, 2000 and the
Designs Rules, 2001.

जारी करने की तिथि : 11/01/2024

Date of Issue : 11/01/2024

Controller General of Patents, Designs and Trade Marks



*पारस्परिकता तारीख (यदि कोई हो) जिसकी अनुमति दी गई है तथा देश का नाम। डिजाइन का स्वत्वाधिकार पंजीकरण की तारीख से दस वर्षों के लिए होगा जिसका विस्तार, अधिनियम एवं नियम के निबंधनों के अधीन, पाँच वर्षों की अतिरिक्त अवधि के लिए किया जा सकेगा। इस प्रमाण पत्र का उपयोग विधिक कार्यवाहियों अथवा विदेश में संजीक्षण प्राप्त करने के लिए नहीं हो सकता है।

The reciprocity date (if any) which has been allowed and the name of the country. Copyright in the design will subsist for ten years from the date of Registration, and may under the terms of the Act and Rules, be extended for a further period of five years. This Certificate is not for use in legal proceedings or for obtaining registration abroad.

ਪਿਛ ਸਪਤਾ ਦੁਕਤ, ਕਾਨੂੰ ਸਰਕਾਰ, ਪੰਜਾਬ ਇੰਡੀਆ ਕਾਲਜ ਅਤੇ ਪੰਜਾਬ ਯੂਨੀਵਰਸਿਟੀ, ਪੰਜਾਬ ਰਾਹਿਲੀ, ਚਾੜ੍ਹੀ ਸੱਤੇ ਵਾਕਾਵਾਲੀ, ਭਾਰਤ ਸਰਕਾਰ, ੬੭੦੦੦੮ ਪਟਿਆਲਾ ਸ਼ਹਿਰ ਪਾਸੋਂ ਲਈ ਕਾਨੂੰ ਸਰਕਾਰ ਦੀ ਅਨੁਮਾਨ ਕੀਤੀ ਗਈ ਹੈ। ਆਪਣੀ ਵੱਡਾ ਕੇਤੇ ਕੁਝ ਅਧਿਕਾਰਾਂ ਵਿੱਚੋਂ ਇੱਕ ਹੈ।