

No. ML1-6103/2019/DC
Drugs Controller & Licensing Authority
Kerala State

Office of the Drugs Controller
Red Cross Road, Vanchiyoor PO
Thiruvananthapuram – 695035
Tel: 0471-2471896, 2473256 (Fax)
Email: dckerala@gmail.com
Website: www.dc.kerala.gov.in

Dated : 07/08/2019

✓ Dr. Subhash Narayanan
Director & CEO
TIMed, MS Valiathan Medical Devices Block
BMT Wing, SCTIMST
Poojappura
Thiruvananthapuram - 695012

Sir,

Sub : Request for clarification on the regulatory status of the product 'ORALSCAN' - reg
Ref : 1. Your application dated 10/04/2019
2. Letter from CDSCO dated 23/07/2019

Kind attention is invited to the references cited.

With reference to your application referred (1), reply has been received from CDSCO informing that the device 'ORALSCAN' is not notified as Drug under Section 3(b)(iv) of the Drugs and Cosmetics Act 1940. The copy of letter received from CDSCO, is also attached for your reference.

Yours faithfully,



Ravi.S.Menon
(Drugs Controller and Licencing Authority)

29/Misc/3/2019-DC (88)

Government of India

Directorate General of Health Services
Central Drugs Standard Control Organization
(Medical Devices and Diagnostic Division)

11303
29/7/19

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

Date: 23 JUL 2019

To

The Drugs Controller
Red Cross Road, Vanchiyoor PO,
Thiruvananthapuram- 695035

SUB: Clarification on the regulatory status of the product- "ORALSCAN" as per Drugs and cosmetic Act, 1940 and Medical Devices Rules, 2017 - regarding

Sir,

Please refer to your letter No. ML1-6103/2019/DC dated 26.04.2019 received by this office vide p-1334325 dated 10.05.2019 on the subject matter.

The matter has been examined in the light of documents submitted by you. In this connection, it is stated that the product viz., **ORALSCAN**, a handheld multispectral imaging camera for screening and detection of oral cancer at the point of care using tissue fluorescence and diffuse reflectance images captured at multiple wavelengths is not notified under section 3 (b) (iv) of Drugs and Cosmetic Act and Rules thereunder.

Yours faithfully,

V.G.S.

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