GOVERNMENT OF KARNATAKA
DRUGS CONTROL DEPARTMENT 1
CERTIFICATE OF PHARMACEUTICAL PRODUCT

No of certificate: DCD/CR-1447/Spl.cell 1 /18-19

G&C No: 17108

Office of drugs controller
For the state of Karnataka
P.B. No.:5377 Palace Road
Bangalore - 560001

Exporting (Certifying Country): INDIA

Importing (Requesting Country): Austria , Argentina , Albania , Algeria, Angola, Brazil ,Bangladesh , Bhutan , Burkina Fasso , Burundi, Cambodia, Canada, Chile, China, Colombia, Congo, Croatia, Cuba, Cyprus, Denmark ,Egypt , Ethiopia, France, Germany , Ghana , Guyana, Hong Kong , Hungary , Indonesia, Iran , Iraq, Israel, Italy , Jordan , Kenya , Korea, Libya, Malaysia, Mexico , Myanmar, Nepal , Nigeria, Panama , Peru , Philippines, Neurto, Puerto, Rico, Russia, Saudi Arabia, Singapore , Srilanka, Sudan , south Africa, Seria, Thailand , Taiwan , Turkey , UAF , UK , USA, Ukraine , Femen , Zambia.

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1. Name and Dosage form of the Product: Absorbable Surgical Suture (Synthetic)
Sterilised Surgical Suture
Monofilament Polydioxanone
UNISYNTH PDS (8-0, 7-0, 6-0, 5-0, 4-0, 3-0, 2-0, 0, 1, 2 )

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1.1 Active Ingredient(s) and amount per unit dose : Not Applicable as the product consists of sterile thread .

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1.2 Is this product licenced to be placed on the market for use in the exporting country? **Yes**
1.3 Is this product actually placed on the market in the exporting country? **Yes**

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**If the answer to question 1.2 is "Yes", Continue with section 2A and omit 2B**

**2A**

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1. Number of Product Licence and date of Issue :
**KTK/28/415/2013 dated 13.07.2015**
Permission Number: DCD/MFG/SR-880/14-15
Dated 28.07.2015
2. Product Licence Holder:
**UNISUR LIFECARE PVT LTD**
**#15/1,2,3. Andrahalli Main Road,**
**Acharya Indl. Complex, Vishwaneedam Post**
**Bangalore -560091**

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3. Status of Licence Holder : a ☒ b ☐ c ☐

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4. Is a summary basis for approval appended : **No**
5. Is the attached officially approved product information

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Complete and consonant with the licence?
Yes ☐ No ☐ Not Provided ☒ 12

6. Applicant for certificate if different from the licence Holder (Name and address) : **Not Applicable**

**2B**

1. Applicant for certificate:
2. Status of applicant : a ☐ b ☐ c ☐ d ☐
2.1 For categories B and C , the name and address of

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the manufacturer, producing the dosage form is :

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3. Why is market authorization is lacking?
Not Required ☐ Not Requested ☐ Under Consideration ☐ Refused ☐

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4. Remarks

VALID UPTO
28 APR 2022

3. Does the certifying authority arrange for periodic inspection of the manufacturing plant in which the dosage form is produce? ☒ Yes No ☐ Not applicable ☐ if no or not applicable proceed to question 4
3.1 Periodicity of routine inspection (Years) : **Once in a year**
3.2 Has the manufacturer of this type of dosage form been inspected? Yes ☒ No ☐ 15
3.3 Do the facilities and operations confirm to GMP as recommended by the world health organization? Yes ☒ No ☐
4. Does the information submitted by the applicant satisfy the certifying authority on all aspects for the manufacture of the

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product? Yes ☒ No ☐ if no Explain: **Not applicable**

Address of the certifying authority:
Drugs Control Department
Palace Road, Bengaluru, India.
Phone no : 22264760, 22374043.
E-mail: dckarnatka@gmail.com
Fax: 22286492

DRUGS CONTROLLER FOR THE STATE OF KARNATAKA

Name of the authorized Person: AMARESH TUMBAGI

Signature
Additional Drugs Controller and Licensing Authority

This certificate conforms to the format recommended by the World Health Organization.
(general instructions and explanatory note overleaf)

19 JUL 2019

AMARESH TUMBAGI
Additional Drugs Controller &
Licensing Authority
Karnataka

**Explanatory notes**

1. This certificate, which is in the format recommended by WHO, establishes the status of the pharmaceutical product and of the applicant for the certificate in the exporting country. It is for a single product only since manufacturing arrangements and approved information for different dosage forms and different strengths can vary.
2. Use, whenever possible, International Nonproprietary Names (INNs) or national nonproprietary names.
3. The formula (complete composition) of the dosage form should be given on the certificate or be appended.
4. Details of quantitative composition are preferred but their provision is subject to the agreement of the product-license holder.
5. When applicable, append details of any restriction applied to the sale, distribution or administration of the product that is specified in the product license.
6. Sections 2A and 2B are mutually exclusive.
7. Indicate, when applicable, if the license is provisional, or the product has not yet been approved.
8. Specify whether the person responsible for placing the product on the market:
    a. manufactures the dosage form;
    b. packages and/or labels a dosage form manufactured by an independent company; or
    c. is involved in none of the above.
9. This information can only be provided with the consent of the product-license holder or, in the case of non-registered products, the applicant. Non-completion of this section indicates that the party concerned has not agreed to inclusion of this information. It should be noted that information concerning the site of production is part of the product license. If the production site is changed, the license has to be updated or it is no longer valid.
10. This refers to the document, prepared by some national regulatory authorities, that summarizes the technical basis on which the product has been licensed.
11. This refers to product information approved by the competent national regulatory authority, such as Summary Product Characteristics (SPC)
12. In this circumstance, permission for issuing the certificate is required from the product-license holder. This permission has to be provided to the authority by the applicant.
13. Please indicate the reason that the applicant has provided for not requesting registration.
    a. the product has been developed exclusively for the treatment of conditions — particularly tropical diseases — not endemic in the country of export;
    b. the product has been reformulated with a view to improving its stability under tropical conditions;
    c. the product has been reformulated to exclude excipients not approved for use in pharmaceutical products in the country of import;
    d. the product has been reformulated to meet a different maximum dosage limit for an active ingredient;
    e. any other reason, please specify.
14. Not applicable means the manufacture is taking place in a country other than that issuing the product certificate and inspection is conducted under the aegis of the country of manufacture.
15. The requirements for good practices in the manufacture and quality control of drugs referred to in the certificate are those included in the thirty-second report of the Expert Committee on Specifications for Pharmaceutical Preparations, WHO Technical Report Series No. 823, 1992, Annex 1. Recommendations specifically applicable to biological products have been formulated by the WHO Expert Committee on Biological Standardization (WHO Technical Report Series, No. 822, 1992, Annex 1).
16. This section is to be completed when the product-license holder or applicant conforms to status (b) or (c) as described in note 8 above. It is of particular importance when foreign contractors are involved in the manufacture of the product. In these circumstances the applicant should supply the certifying authority with information to identify the contracting parties responsible for each stage of manufacture of the finished dosage form, and the extent and nature of any controls exercised over each of these parties.