



GIÁM ĐỐC
Nguyễn Thị Huyền



Certificate of Compliance

We hereby declare that the technical file of product complied with the requirement of directives Medical Device Regulation (EU 2017/745)

Applicants

Name : OMKARA CORP
Brand name : EPIGLUE

Address : A-852E, SUSHANT LOK-1, GURGAON, HARYANA, 122002, INDIA

Product : EPIGLUE (0.10/0.15/0.25/0.5 mL) – TOPICAL SKIN ADHESIVE – CLASS I – STERILE
EPIGLUE ADVANCED (0.25 mL) – TOPICAL SKIN ADHESIVE – CLASS I – STERILE

Complies with the requirements applicable to it

The Certification body has performed an audit of the above product quality system covering the design, manufacture and final inspection of the certified product. The quality system has been assessed, approved and is subject to continuous surveillance according to the directives Medical Device Regulation (EU 2017/745)

This certificate is issued under the following conditions:

It applies only to the quality system maintained in the manufacture of above referenced models and it does not substitute the design or type-examination procedures, if requested.

1. The certificate remains valid until the manufacturing conditions or the quality systems are changed.
2. The certificate validity is conditioned by positive results or surveillance audits.
3. After fulfilling the relevant EU legislation, the manufacturer shall affix to each device, of the above referenced models.
4. The CE mark as shown above can be used, under the responsibility of the manufacturer, after completion of an EC Declaration of conformity and compliance with all relevant EC Directives. The statement is based on a single evaluation of one sample of above mentioned product. It does not imply an assessment of the whole production.

Certificate No. QVA-OACP-21-233580

Certificate can be verified at www.gaafs.us

Date of Certification

1st Surveillance Due

2nd Surveillance Due

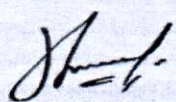
Certificate Expiry (Subject to the company maintaining its system To the required standard)

23TH September 2021

22TH September 2022

22TH September 2023

22TH September 2024


Authorized Signatory



QVA Certification

CAB Address : Maryland Avenue, SW Washington, D.C. 20202

Validity of this certificate is subject to annual surveillance audits to be done successfully

This certificate is the property of QVA Certification and shall be return immediately on request

QVA Certification is an independent Systems Products and Personal assessment Body, QVA Certification is accredited by GAAFS.US