



Certificate of Compliance

We hereby declare that the technical files of all the items in each product group of complied with the requirements of the Medical Device Directive EU Directive 93/42/EEC

Certificate No.: CE-3616

Manufacturer

Name : K D SHELARAK

Address: Shop-107, Shubh laxmi Shopping Centre Complex, Sector-9,

Vasant Nagri, Vasai East, Palghar, Maharashtra-401208, India

Product

Name : Medical Devices

Description: As per appendix page-I

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 Medical Device Directive EU Directive 93/42/EEC

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.
- 2. The certificate remains valid until the manufacturing conditions or the quality systems are not changed.
- 3. The certificate validity is conditioned by positive results of surveillance audits.

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.

Validity of this certificate can be verified at www.ukcertifications.co.uk/verify

Date of Certification 28th September 2018

1st Surveillance Audit Due 27th September 2019

2nd Surveillance Audit Due 27th September 2020

Certificate Expiry (subject to the company maintaining its 27th September 2021

system to the required standard)

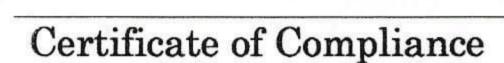
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Authorised Signatory

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Appendix-I

Appendix to Certificate no.: CE-3616

Manufacturer:

K D SHELARAK

Address:

Shop-107, Shubh laxmi Shopping Centre Complex,

Sector-9, Vasant Nagri, Vasai East, Palghar,

Maharashtra-401208, India

This certificate referred to above covers the following products like:

Products:

- SHELARAK 400
- SHELARAK 400VS
- SHELARAK 200
- SHELARAK M 500

Authorised Signatory



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