

Certificate of Compliance

We hereby declare that the technical file of product complied with the requirement of directives Medical Devices Directive 93/42/EEC

Applicants

Name Address : RELIFE ORTHO

: PANCHRANTNA IND. PARK, 20-21, OPP. AVDESH IND. HUB BHAVDA GAM ROAD, AHMEDABAD-INDOOR HIGHWAY DASKROI AHMEDABAD-382433, GUJARAT, INDIA

Product

: "BONE SCREW, BONE PLATE, INTRAMEDULLARY NAIL, SPINAL IMPLANT, MAXILLOFACIAL, PINS / WIRES, PROSTHESIS IMPLANTS, TRAUMA IMPLANT, ARTHROSCOPY IMPLANTS, HAND AND FOOT IMPLANTS, EXTERNAL FIXATION, INSTRUMENT SETS"

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 Devices 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.

- 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 product, 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-RLHV-23-0724173

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 07TH AUGUST 2023 06TH AUGUST 2024 06TH AUGUST 2025 06TH AUGUST 2026

Registere

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 returned immediately on request QVA Certification is an independent Systems Products and Personal assessment Body, QVA Certification is a accredited by GAAFS.US