



Certificate of Compliance

We hereby declare that the technical file of Class 1 product complied with the requirement of the Medical Council Directive 93/42/EEC of June 1993.

Manufacturer

Name : **Jiangxi Hengte Industry Company
(Sri Chin Holdings (Pvt) Ltd)**

Address : **No. 297/5, Colombo Road, Kahathuduwa, Polgasovita, 10320,
Sri Lanka**

Product : **Elastic Crepe Bandage - 7.5cmx4.5m, 10cmx4.5m**

Testing Standard : **ISO 14704-1:2005, ISO 1833, ISO 7211-2, ISO 3801 Requirements**

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 the Medical Council Directive 93/42/EEC of June 1993.

This certificate is issued under the following conditions:

1. 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 or surveillance audits.
4. After fulfilling the relevant EU legislation of class 1, the manufacturer shall affix to each device, of the above referenced models.
5. The CE mark as shown below 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

Date of Registration : 30 December 2020
1st Surveillance Due : 29 December 2021
2nd Surveillance Due : 29 December 2022
Certificate Expiry (subject to the company maintaining its system to the required standard) : 29 December 2023

Certificate No:- 201230605

To Verify this certificate please visit at www.otabucert.co.uk




Authorised Signatory

Otabu Certification Limited (UK)

Validity of this Certificate is subject to Annual Surveillance audits done successfully

This Certificate of Registration remains the Property of Otabu Certification Limited and shall be returned immediately upon request.

Email:- info@otabucert.co.uk Website:- www.otabucert.co.uk

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