



This is to certify that the Quality Management System of

Anji Hongde Medical Products Co., Ltd.

Unified Social Credit Code : 91330523785653430W

Operation Address : Building No. 1,3,4,5, Bamboo Industrial Zone, Xiaofen Town, Anji County, Huzhou City, Zhejiang Province, China

Registered Address : Building No. 1,3,4,5, Bamboo Industrial Zone, Xiaofen Town, Anji County, Huzhou City, Zhejiang Province, China

applicable to

Production and Sales of Plaster of Paris Bandage (Viscose Form), Elastic Bandage, Adhesive Bandage, Cast Padding, Casting Tape, Casting Splint and Tongue Depressor(Within the Scope of License Qualification)

has been assessed and registered by NQA against the provisions of

ISO 13485: 2016

This registration is subject to the company maintaining a quality management system, to the above standard, which will be monitored by NQA.

Certified Clients shall accept regular surveillance assessments, the validity of certificates shall be maintained for the positive result of audit.

The information of this certificate can be checked on CNCA's website (www.cnca.gov.cn) SNQA's website : www.snqa.com.cn

M Comley

Managing Director



Certificate Number **43776**

Date: 18 August 2017
Reissue Date: 31 October 2018
Valid Until: 31 October 2021
EAC Code: 04/14/17



CE Technical Documentation Review Report

Manufacturer: Anji Hongde Medical Products Co., Ltd.
Building No.1,3,4,5, Bamboo Industrial Zone,
Xiaofeng Town, Anji County, Huzhou City, Zhejiang
313301, China

Report Number: 15096030 001

Examination intent: Examination the completeness of the Technical Documentation according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII

Product(s): See attachment

Type(s)/Model(s): Various Sizes

Classification: Class I
(according to manufacturer's declaration)

Review result: During the examination of the provided Technical Documentation (see attachment), no Non-compliance according to the requirements of the Medical Devices Directive 93/42/EEC Annex VII was detected.

TÜV Rheinland (Shanghai) Co., Ltd.

Shanghai, 2016-08-25



Daniel ZHU
Lead Auditor, Product Assessor
Medical Device Services

