

JIANGXI HONGDA MEDICAL EQUIPMENT GROUP LTD.

NO.39 South Shengli Road, Jinxian County Jiangxi Province P R China
Tel:0086-791-85628818 Fax:0086-791-85628819
http: www.jxhd.cn Email:hongda008@jxhd.cn

EC DECLARATION OF CONFORMITY

DATE: 2016-08-15

We Jiangxi Hongda Medical Equipment Group Ltd . hereby declare that the product, details of which are given below, is manufactured by us.

**Manufacturer: Jiangxi Hongda Medical Equipment Group Ltd .
No.39 South Shengli Road , Jinxian County ,Jiangxi Province , China**

Produce Name: hypodermic needle

Brand Name: “HELMED”

Sizes:18G/21G/22G

CLASSIFICATION: II a

Confirms To the following standards

Specifications In House Standarts

EC-PEPRESENTATIVE: Shanghai International Holding.corp.GmbH(Europe)

ADD: EiffestraBe 80 20537 Hamburg.Germany

ISSUED BY: TUV Rheinland

EN ISO 2000 quality syringe medical devices particular requirement for the application of 13485 ISO: 2003 CERTIFICATE NO:Q1N 015 09 44803 024

The produces are in conformity with the requirements of Medical Devices Council Directive 93/42/EEC ANEX V ARTICLE3

Year of CE Marking: 2015

CERTIFICATED NO: G1 16 05 44803 027

General Manager: Hui Wang

Quality System Manager: Xiaohua Yang