

DECLARATION OF CONFORMITY TO COUNCIL DIRECTIVE 93/42/EEC CONCERNING MEDICAL DEVICES



MANUFACTURER:

Jiangxi Hongda Medical Equipment Group Ltd.
39 South Shengli RD, Jinxian County, Nanchang City, Jiangxi
Province, P.R.China, 331700

MEDICAL DEVICE:

syringes for single use

SPECIFICATION:

1mL, 2mL, 2.5 mL, 3 mL, 5 mL, 10 mL, 20 mL, 30 mL, 50 mL,
60 mL, 100 mL

CLASSIFICATION - ANNEX IX:

Class IIa, Rule 6

CONFORMITY ASSESSMENT ROUTE:

MDD 93/42/EEC Annex II.3

WE, JIANGXI HONGDA MEDICAL EQUIPMENT GROUP LTD, HERE WITH DECLARE THAT THE STATED MEDICAL DEVICE
MEET THE TRANSPOSITION INTO NATIONAL LAW, THE PROVISIONS OF COUNCIL DIRECTIVE 93/42/EEC
CONCERNING MEDICAL DEVICES;

ALL SUPPORTING DOCUMENTATION IS RETAINED AT THE PREMISES OF THE MANUFACTURER, AND THE MANUFACTURER
IS EXCLUSIVELY RESPONSIBLE FOR THE DECLARATION OF CONFORMITY.

NOTIFIED BODY:

TÜV SÜD PRODUCT SERVICE GMBH
RIDLERSTR 65, D-80339 MÜNCHEN, GERMANY

IDENTIFICATION NUMBER

CE 0123

(EC) CERTIFICATE(S):

G1 044803 0031 Rev. 01

EXP. DATE:

<2022-12-03>



EUROPEAN REPRESENTATIVE:

Shanghai International Holding Corp. GmbH(Europe)
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START OF CE-MARKING:

<2005-09-16>

PLACE, DATE OF DECLARATION:

<NAN CHANG>, 2019-04-01

SIGNATURE:

NAME: MS. YANG XIAO HUA

POSITION:

QUALITY MANAGEMENT/ REPRESENTATIVE

LOT 20200326; EXP 20250326; MFG 20200326