

CE technical documents

Document Name: Declaration of Conformity

Document No.: YDS /CE -12

Document Version No.: B/2

Controlled State: Confidential Document



Prepared by: Yu Gang Date: 2020.3.3

Checked by: Luo JieSong Date: 2020.3.3

Approved by: Jin Hui Date: 2020.3.5



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Prepared	Yu Gang	Checked	Luo JieSong	Date	2020.3.3
Approved	Jin Hui	Date	2020.3.5	Effective Date	2020.3.5

1 Summarize

According to the requirement of the Council Directive 93/42/EEC of 14th June 1993 concerning medical devices, amended by Council Directive 2007/47/EC, the company legal representative and authorized European representative declare in our own responsibility that the product meets the provisions of the Council Directive 93/42/EEC of 14th June 1993 concerning medical devices, amended by Council Directive 2007/47/EC. All supporting documentation is retained under the premises of the manufacturer (head of Quality department).

2 Manufacturer:

Name: Anhui Hongyu Wuzhou Medical Manufacturer Co., Ltd.

Address: No.2 Guanyin Road, Economic Development Zone, Taihu County, 246400 Anqing City, Anhui Province, China

Tel: +860556-5129678 Fax: +860556-4249999 Post: 246400

3 Authorised european representative:

Name: Shanghai International Holding Corp. GmbH (Europe)

Address: Eiffestrasse 80, 20537 Hamburg, Germany

Tel: 0049-40-2513175

Fax: 0049-40-255726

4 Medical device:

Sterile insulin syringe for single use

5 Size

The sizes sterile insulin syringe for single use are 0.3ml(U-40)、0.5ml(U-40)、1ml(U-40); 0.3ml(U-100)、0.5(U-100)、1ml(U-100).

The size of the needles are 0.25mm、0.3mm、0.33mm、0.36mm、0.4mm、0.45mm.

6 Applicable standard(s):

ISO8537: 2016

ISO 9626: 2016

7 Umdn Code:

Disposal sterile insulin syringe: 13941

Sterile hypodermic needles for single use: 12745



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8 Classification : IIa (Rule 6, Annex IX, MDD 93/42/EEC)

9 Product conformity assessment

My company production of sterile insulin syringe for single use which belongs to a product IIa, According to the 93/42/EEC amended by 2007/47/EC appendix V, appendix VII EC declaration of conformity procedure to select the authentication way, additional CE mark.

10 Declaration Content

The product concerned has been designed and manufactured under a quality management system according to Annex V of directive MDD93/42/EEC&2007/47EC. Compliance of the designated product with the Directive 93/42/EEC All CE technical documents have been promised its authenticity by our company, we are solely responsible for the documents.

11 Applicable directives

General applicable directives: COUNCIL DIRECTIVE 93/42/EEC of 14 June 1993 concerning Medical devices, amended by Council Directive 2007/47/EC.

12 Applicable standard(s)

EN ISO15223-1:2016	EN 556-1: 2001/AC: 2006、	EN 1041-2008+A1-2013
EN ISO 11135: 2014、	EN ISO 10993-1: 2018	ISO 9626-2016
EN ISO 10993-4: 2017、	EN ISO 10993-5: 2009、	EN ISO 10993-7: 2008/AC: 2009、
EN ISO 10993-10: 2010、	EN ISO 10993-11: 2018、	EN ISO 10993-12: 2012、
EN ISO 11138-2: 2017、	EN ISO 14971: 2012 、	EN ISO11607-1: 2017、
EN ISO 11607-2-2017	EN ISO 11140-1: 2014、	ISO8537: 2016

13 Notified Body:

TÜV SÜD Product Service GmbH
Ridlerstraße 65, 80339 Munich.Germany.

NB with Identification number: 0123

(EC) Certificate(s) number: G2 081232 0010 Rev.02

Certificate Valid until: 2024-05-26



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Effective date of CE Labelling: 2020-03-03

Signature: zhang hong yu

Name: Zhang Hongyu

Position: General Manager

