

CE technical documents

Document Name: Declaration of Conformity

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Controlled State: Confidential Document

Prepared by: Yu Gang Date: 2022.3.3

Checked by: Luo JieSong Date: 2022.3.3

Approved by: Jin Hui Date: 2022.3.5



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Prepared	Gang Yu	Checked	JieSong Luo	Date	2022.3.3
Approved	Jin Hui	Date	2022.3.5	Effective Date	2022.3.5

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:

Hypodermic Safety Needle with Syringe

5 Size


The sizes Hypodermic Safety Needle with Syringe are 1ml、2ml、2.5mL、3ml、5ml、10ml、20ml、30 ml、50 ml、60 ml、100mL;

0.3mm(30G Yellow)、0.33mm(29G Red)、0.36mm (28G Blue-green)、0.4mm(27G Cool grey)、0.45mm(26G Brown)、0.5mm(25G Orown)、0.55mm(24G Purple)、0.6mm(23G Blue)、0.7mm(22G Black)、0.8mm(21G Green)、0.9mm(20G Yellow)、1.1mm(19G Cream)、1.2mm(18G Pink).

6 Applicable standard(s):

ISO7864:2016 Sterile hypodermic needles for single use-Requirements and test methods

ISO 9626:2016 Stainless steel needle tubing for manufacture of medical devices-Requirements and

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test methods

ISO 7886-1:2017 Sterile Syringes for Single Use with needles —Part 1:Syringes for manual use

7 Umdn Code:

Sterile Syringes for Single Use with needles: 13929

Sterile safety hypodermic needles for single use: 12745

8 Classification :

According to 93/42 / EEC (Amended by 2007/47 / EC) the European medical devices directive principles of classification, this company produces the Hypodermic Safety Needle with Syringe belongs to II class a product.

9 Product conformity assessment

Our company belongs to the production of the Hypodermic Safety Needle with Syringe II class a products, according to 93/42 / EEC (Amended by 2007/47 / EC) the European medical devices directive in appendix IX rule 6 relevant EC, conforming to the declaration procedures to select additional CE mark.

10 Declaration Content

The product concerned has been designed and manufactured under a quality management system according to Annex I 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 Harmonized standard(s)

MDD93/42/EEC	ISO 10993-1:2018	EN ISO 10993-4:2017	EN ISO 10993-5:2009
EN ISO 13485-2016	EN ISO 10993-7:2009	ISO 10993-10:2021	EN ISO 10993-11:2018
ISO 14971:2019	EN ISO 11607-1:2020	EN ISO 11607-2:2020	ISO/TR 24971:2020
EN ISO 11737-1:2018	EN ISO 11140-1:2014	EN ISO 11138-2:2017	ISO7864:2016
EN ISO 11135-2014	ISO 14644-1-2015	ISO7886-1:2017	MEDDEV2.7.1-4
ISO 80369-7-2016	ISO 9626-2016	YY/T0243 — 2016	EN ISO15223-1:2016
ISO 6009: 2016	ISO15510:2014	ASTM F1980-16	ISO 23908-2011
YY/T 0242-2007	EN 556-1: 2001/AC: 2006	EN 1041-2008+A1-2013	



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13 Notified Body:

TÜV SÜD Product Service GmbH

Ridlerstraße 65, 80339 Munich, Germany.

NB with Identification number: 0123

Signature: *Zhang Hongyu*

Name: Zhang Hongyu

Position: General Manager

