

## CE technical documents

**Document Name: Declaration of Conformity**

**Document No.: AQZSZ /CE -12**

**Document Version No.: A/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**



	<b>Sterile safety hypodermic needles for single use</b>			<b>Doc. No.</b>	<b>AQZSZ/CE-12</b>
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<b>Prepared</b>	<b>Gang Yu</b>	<b>Checked</b>	<b>JieSong Luo</b>	<b>Date</b>	<b>2020.3.3</b>
<b>Approved</b>	<b>Jin Hui</b>	<b>Date</b>	<b>2020.3.5</b>	<b>Effective Date</b>	<b>2020.3.5</b>

## 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 safety hypodermic needles for single use

## 5 Size


The sizes sterile safety hypodermic needles for single use are 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 test methods



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### 7 Umdn Code:

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 Sterile safety hypodermic needles for single use belongs to II class a product.

### 9 Product conformity assessment

Our company belongs to the production of the Sterile safety hypodermic needles for single use 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)

EN ISO15223-1: 2016	EN 1041-2008+A1-2013	EN 556-1: 2001/AC: 2006
EN ISO 11135:2014	EN ISO 10993-1:2018	EN ISO 10993-4:2017
EN ISO 10993-5:2009	EN ISO 10993-10:2010	EN ISO 11607-2:2017
EN ISO 10993-11:2018	EN ISO 10993-12:2009	MEDDEV2.7.1-4
EN ISO 14971:2012	EN ISO 11607-1:2017	EN ISO 13485:2016
EN ISO 11737-1:2018	EN ISO 11140-1:2014	EN ISO 11138-2:2017
ISO7864: 2016	ISO 9626-2016	EN ISO 10993-7: 2008 +AC:2009

### 13 Notified Body:

TÜV SÜD Product Service GmbH  
Ridlerstraße 65, 80339 Munich.Germany.  
NB with Identification number: 0123



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

Certificate Valid until: 2024-05-26

Effective date of CE Labelling: 2020-03-03

Signature: Zhang Hongyu

Name: Zhang Hongyu

Position: General Manager

