

# **EC DECLARATION OF CONFORMITY**

The following EC declaration of conformity exemplifies the required content according to Directive 93/42/EEC.

## EC DECLARATION OF CONFORMITY

Name and Address of the Manufacturer: **Jiangsu Micsafe Medical Technology Co., Ltd**  
**Xituan Industrial Park, Dafeng District, Yancheng, 224125,**  
**Jiangsu, China**  
**European Representative: Share Info Consultant Service LLC**  
**Repräsentanzbüro**  
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**Dimdi Code DE/0000047946**  
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Medical Device: **Sterile Syringe**

Class: **IIa**

according to annex IX of directive 93/42/EEC

meets the provisions of the directive 93/42/EEC and its transpositions in national laws which apply to it. The declaration is valid in connection with the "final inspection report" of the device.

Conformity Assessment Procedure: **Directive 93/42/EEC Annex V**

Registration No.: **DD 60147126 0001**  
**Issue date: 2020-05-03**  
**Expiry date: 2024-05-26**

Notified Body: **TÜV Rheinland LGA Products GmbH**  
**Tillystraße 2**  
**90431 Nürnberg**  
**Deutschland**  
**CE 0197**

| Product         | Model/Type              |                  | Capacity | OD                      | Length    |             |
|-----------------|-------------------------|------------------|----------|-------------------------|-----------|-------------|
| Sterile Syringe | with needle             | Center Luer Slip | 1ml      | 25G/26G/27G/28G/29G/30G | 13~38mm   | 1/2"~1 1/2" |
|                 |                         |                  | 2ml      | 21G/22G/23G/25G         | 13~38mm   | 1/2"~1 1/2" |
|                 |                         |                  | 2.5ml    | 21G/22G/23G/25G         | 13~38mm   | 1/2"~1 1/2" |
|                 |                         |                  | 3ml      | 20G/21G/22G/23G/25G     | 13~38mm   | 1/2"~1 1/2" |
|                 |                         |                  | 5ml      | 20G/21G/22G/23G         | 13~38mm   | 1/2"~1 1/2" |
|                 |                         |                  | 10ml     | 20G/21G/22G/23G         | 25.4~38mm | 1"~1 1/2"   |
|                 | with unassembled needle | Center Luer Slip | 1ml      | 25G/26G/27G/28G/29G/30G | 13~38mm   | 1/2"~1 1/2" |
|                 |                         |                  | 2ml      | 21G/22G/23G/25G         | 13~38mm   | 1/2"~1 1/2" |
|                 |                         |                  | 2.5ml    | 21G/22G/23G/25G         | 13~38mm   | 1/2"~1 1/2" |
|                 |                         |                  | 3ml      | 20G/21G/22G/23G/25G     | 13~38mm   | 1/2"~1 1/2" |
|                 |                         |                  | 5ml      | 20G/21G/22G/23G         | 13~38mm   | 1/2"~1 1/2" |
|                 |                         |                  | 10ml     | 20G/21G/22G/23G         | 25.4~38mm | 1"~1 1/2"   |
|                 |                         |                  | 20ml     | 18G/20G/21G/22G         | 25.4~38mm | 1"~2"       |
|                 |                         |                  | 30ml     | 18G/20G/21G/22G         | 25.4~50mm | 1"~2"       |
|                 |                         |                  | 50ml     | 18G/20G/21G             | 25.4~50mm | 1"~2"       |
|                 |                         |                  | 60ml     | 18G/20G/21G             | 25.4~50mm | 1"~2"       |
|                 | with needle             | Side Luer Slip   | 10ml     | 20G/21G/22G/23G         | 25.4~38mm | 1"~1 1/2"   |
|                 | with unassembled needle | Side Luer Slip   | 10ml     | 20G/21G/22G/23G         | 25.4~38mm | 1"~1 1/2"   |
|                 |                         |                  | 20ml     | 18G/20G/21G/22G         | 25.4~38mm | 1"~2"       |
|                 |                         |                  | 30ml     | 18G/20G/21G/22G         | 25.4~50mm | 1"~2"       |
|                 |                         |                  | 50ml     | 18G/20G/21G             | 25.4~50mm | 1"~2"       |
|                 |                         |                  | 60ml     | 18G/20G/21G             | 25.4~50mm | 1"~2"       |
|                 | with needle             | Luer Lock        | 2ml      | 21G/22G/23G/25G         | 13~38mm   | 1/2"~1 1/2" |
|                 |                         |                  | 2.5ml    | 21G/22G/23G/25G         | 13~38mm   | 1/2"~1 1/2" |
|                 |                         |                  | 3ml      | 20G/21G/22G/23G/25G     | 13~38mm   | 1/2"~1 1/2" |
|                 |                         |                  | 5ml      | 20G/21G/22G/23G         | 13~38mm   | 1/2"~1 1/2" |
|                 |                         |                  | 10ml     | 20G/21G/22G/23G         | 25.4~38mm | 1"~1 1/2"   |
|                 |                         |                  | 20ml     | 18G/20G/21G/22G         | 25.4~38mm | 1"~2"       |
|                 | with unassembled needle | Luer Lock        | 1ml      | 25G/26G/27G/28G/29G/30G | 13~38mm   | 1/2"~1 1/2" |
|                 |                         |                  | 2ml      | 21G/22G/23G/25G         | 13~38mm   | 1/2"~1 1/2" |
|                 |                         |                  | 2.5ml    | 21G/22G/23G/25G         | 13~38mm   | 1/2"~1 1/2" |
|                 |                         |                  | 3ml      | 20G/21G/22G/23G/25G     | 13~38mm   | 1/2"~1 1/2" |
|                 |                         |                  | 5ml      | 20G/21G/22G/23G         | 13~38mm   | 1/2"~1 1/2" |
|                 |                         |                  | 10ml     | 20G/21G/22G/23G         | 25.4~38mm | 1"~1 1/2"   |
|                 |                         |                  | 20ml     | 18G/20G/21G/22G         | 25.4~38mm | 1"~2"       |
|                 |                         |                  | 30ml     | 18G/20G/21G/22G         | 25.4~50mm | 1"~2"       |
|                 |                         |                  | 50ml     | 18G/20G/21G             | 25.4~50mm | 1"~2"       |
|                 |                         |                  | 60ml     | 18G/20G/21G             | 25.4~50mm | 1"~2"       |

Yan cheng / 2013.04.04.  
Place and Date

Drolna dong / PRRC  
Name and Function