Jiangsu Micsafe Medical Technology Co., Ltd

Manufacturer's Declaration

According to Regulation (EU) 2023/607, amending Regulation (EU) 2017/745 (MDR) and regarding the transitional provisions.

Name of Manufacturer：Jiangsu Micsafe Medical Technology Co.,Ltd
Address of Manufacturer：Xituan Industrial Park, Dafeng District, Yancheng City, Jiangsu Province 224125, China

Declares the amendments to Article 120 of the MDR, as set out in Art. 1 of Regulation (EU) 2023/607, apply to the following devices:

CE Certificate Registration Number	DD601471260001
CE Certificate Report Number	17054682002
Quality Management System （EN ISO 13485:2016） Certificate Registration No.	SX2144287-1
Expire date：	2025-12-26
Notified Body (MDD)	TÜV Rheinland LGA Products GmbH
Notified Body Address:	Tillystraße 2 90431 Nürnberg Deutschland
Notified Body number: (MDD)	CE 0197

Medical device information			
Name of Devices	Device Class	EMDN code	Classification Rule including subclause according to Annex VIII
Hypodermic needle	Class IIa	A0101010102	

The manufacturer declares that the following conditions laid down in Regulation (EU) 2023/607 are met:

1. The MDD Certificates of the products issued from 25 May 2017 that were still valid on 26 May 2021 and that have not been withdrawn afterwards;Our CE certificate was issued 2020-05-03, due 2024-05-26,

2. Those products continue to comply with MDD;

3. There are no significant changes in the design and intended purpose of the products;

4. The products do not present an unacceptable risk to the health or safety of patients, users or other persons, or to other aspects of the protection of public health;

5. we have established a quality management system according to MDR Article 10 (9).

6. The requirements of MDR relating to postmarket surveillance, market surveillance, vigilance, registration of economic operators and of device shall apply to the products,

7. We have signed a written agreement with a notified body in accordance with MDR for the conformity assessment; agreement number: .....

Therefore, as per Article 1 (1), paragraph (b) of Regulation (EU) 2023/607, the above listed devices can be placed on the market in the EU market and any other territories accepting CE marked devices, the MDD deadline was extended to 31 December 2028.

Company name:

Jiangsu Micsafe Medical Technology Co., Ltd

Company Representative：Tony Yang

Position: CEO

Signature Tony Yang

Date：2025-07-01