

Changzhou Shuangma Medical Devices Co., Ltd.  
San He Kou Development Zone, Zhenglu,  
Tianning, 213115 Changzhou, Jiangsu,  
China

Your ref.  
Our ref. MED/24-7387380  
Tel. +31 88 96 83 009  
Fax +31 88 96 83 100  
E-mail [medical.nl@dekra.com](mailto:medical.nl@dekra.com)

Arnhem, 7 February 2024

Subject: Notified Body Confirmation Letter

To whom it may concern,

**Confirmation of the status of a formal application, written agreement, and appropriate surveillance in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices**

This letter confirms that, DEKRA Certification B.V., a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0344 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and has signed a written agreement (dated 8 May 2023) in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

Changzhou Shuangma Medical Devices Co., Ltd.  
San He Kou Development Zone, Zhenglu,  
Tianning, 213115 Changzhou, Jiangsu,  
China  
SRN Number: CN-MF-000009732

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables below. Table 1 identifies the devices for which an MDR application has been received, written agreement concluded and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. Table 2 identifies the devices for which an MDR application has been received and a written agreement

concluded, but the NB has not yet taken the responsibility for appropriate surveillance of the corresponding devices under the applicable Directive.

In the case of devices covered by certificates issued under Directive 90/385/EEC (AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation or exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR respectively, by the 20 Mar 2023 for the relevant devices.

The transition timelines that apply to the devices covered by this letter, subject to the manufacturer's continued compliance to the other conditions specified in Article 120.3c of MDR (as amended by (EU) 2023/607), are shown below:

- 26 May 2026 for Class III custom-made implantable devices
- 31 December 2027 for Class III devices and Class IIb implantable devices excluding Well-established technologies (WET - sutures, staples, dental fillings, dental braces, tooth crowns, screws, wedges, plates, wires, pins, clips and connectors)
- 31 December 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- 31 December 2028 for devices not requiring the involvement of a notified body under MDD but requiring it under MDR (e.g., class I devices that qualify as re-usable surgical instruments)

On behalf of the Notified Body,



Ms. Xiaoli Ren  
Project Manager

**Table 1: Devices covered by this letter and for which the NB is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Sterile Syringes for Single Use	Class IIa	N/A	Certificate # 6054198CE01; NB# 0344
Sterile Infusion Sets for Single Use	Class IIa	N/A	Certificate # 6054198CE01; NB# 0344
Sterile Burette Infusion Sets for Single Use	Class IIa	N/A	Certificate # 6054198CE01; NB# 0344
Sterile Hypodermic Needles for Single Use	Class IIa	N/A	Certificate # 6054198CE01; NB# 0344
Cervical Samplers	Class IIa	N/A	Certificate # 6054198CE01; NB# 0344
Vaginal Speculums for Single Use	Class Is	N/A	Certificate # 6054198CE01; NB# 0344

**Table 2: Devices covered by this letter and for which the NB is NOT responsible for appropriate surveillance of the corresponding devices under the applicable Directive:**

Device name or Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If the MDR device is a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
N/A	N/A	N/A	N/A

### Confirmation Letter Revision History

Date	Certification Notice (No. + Ver.)	Action
2024-02-07	6048800CN07.1	Initial issue