Declaration of Conformity
According to Medical Device Directive (MDD) 93/42/EEC

Device trade name and model/order number

Description	DROH article code	Manufacturer REF
Silicone tube with connecting sleeve	12-AMD-5/9	12-AMD-5/9
Connector series	131-XOPC--XXX	LY27-00XX
Silicone breathing tube 22/22mm series	091-EGSC-XXXX	SUTXXX-22/22-19
Silicone breating tube 10/10mm series	091-KKSC-XXXX	SUTXXX-10/10-19
Silicone breating tube 22/10mm series	091-KUSC-XXX	SUTXXX-22/10-19
Silicone tube series	121-MRSC-5XXXX	NUT0X.0XXX.0S60
Silicone tube series with X-Ray line	121-MXSC-9XXX	XRT0X.0XXX.0S60

Device classification

II a

Manufacturer name and address

Jinan Chensheng Medical Technology Co., Ltd.
No. 18- 20 Lashan Road, Shizhong District
Jinan Shandong Province
250022 Jinan
China

Notified Body name and ID number

Ente Certificazione Macchine srl
Via Ca´Bella 243
40053 Valsamoggia (BO)
Italy

CE 1282

CE certificate number

ECM18MDD013 Rev. 1

Date CE Marking was first applied

24.07.2018

Expiry Date of CE certificate

23.07.2023

Authorized EC Representative contact information

Luxus Lebenswelt GmbH
Kochstr. 1
47877 Willich
Germany

Route to compliance

Annex II

Standards applied

(Besides harmonized standards: http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/medical-devices/index_en.htm)

济南晨生医疗科技有限公司 JINAN CHENSHENG MEDICAL TECHNOLOGY CO., LTD

JINAN CHENSHENG MEDICAL TECHNOLOGY CO., LTD 济南晨生医疗科技有限公司

Name and signature of authorized company officer

Winnie

Ente Certificazione Macchine

Notified Body n. 1282 - Testing Laboratory ISO/IEC 17025 n. 1515L
Authorized Training Body n. 6737 - Inspection Body

CONFIRMATION LETTER IN THE FRAMEWORK OF REGULATION EU 2023/607

FOR "LEGACY" DEVICES ACCORDING TO DIRECTIVE 93/42/EEC

REFERENCE N° 04/F

ENTE CERTIFICAZIONE MACCHINE SRL
Via Ca' Bella, 243 – Loc. Castello di Serravalle – 40053 Valsamoggia (BO) – Italy
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ENTE CERTIFICAZIONE MACCHINE

Jinan Chensheng Medical Technology Co., Ltd

Single Registration Number: CN-MF-000016827
Address: No. 18-20 Lashan Road, Shizhong District Jinan, Shandong Province, P.R. China
Referent: Mrs. Winnie

CONFIRMATION LETTER IN THE FRAMEWORK OF REGULATION EU 2023/607

FOR "LEGACY" DEVICES
ACCORDING TO DIRECTIVE 93/42/EEC

Confirmation of the status of a formal application, written agreement, and appropriate surveillance activity 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

Ente Certificazione Macchine srl (ECM), a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **1282 on NANDO**, confirms to have received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR and to have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with **Jinan Chensheng Medical Technology Co., Ltd**

In addition, this letter confirms that **ECM**, where relevant, has signed a written agreement with **Jinan Chensheng Medical Technology Co., Ltd** governing transfer of the surveillance activitiy in accordance with Article 120, paragraph 3e of MDR as amended by Regulation (EU) 2023/607.

The devices covered by the formal application and the written agreements mentioned above are identified in the Tables below. **Table 1** identifies devices for which an MDR application has been received, written agreement concluded, and for which **ECM** is also responsible for appropriate surveillance of the corresponding devices under the applicable Directive. **Table 2** identifies devices for which an MDR application has been received and a written agreement concluded, but **ECM** 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 repectively, by 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 120.3 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)

ENTE CERTIFICAZIONE MACCHINE SRL
LUCA BEDONNI

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

Device name	MDR Device classification	If a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application
Medical Silicone Rubber Tube	☐ Class IIb device ☒ Class IIa device ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments	☐ MDD/AIMDD device identification: ☒ Not applicable	☒ MDD/AIMDD Certificate ECM18MDD013 rev.1 issued by Ente Certificazione Macchine srl, NB number 1282 ☐ Not applicable
Silicone Breathing Circuit	☐ Class IIb device ☒ Class IIa device ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments	☐ MDD/AIMDD device identification: ☒ Not applicable	☒ MDD/AIMDD Certificate ECM18MDD013 rev.1 issued by Ente Certificazione Macchine srl, NB number 1282 ☐ Not applicable

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

Device name	MDR Device classification (as proposed by the manufacturer and verified at the pre-application stage)	If a substitute device, identification of the corresponding MDD/AIMDD device	MDD/AIMDD Certificate Reference(s) of the devices under MDR application
//	☐ Class IIb device ☐ Class IIa device ☐ Class I devices placed on the market in sterile condition ☐ Class I devices with a measuring function ☐ Class I devices that qualify as re-usable surgical instruments	☐ MDD/AIMDD device identification: // ☐ Not applicable	☐ MDD/AIMDD Certificate Certificate number issued by NB name and NANDO number ☐ Not applicable