Manufacturer's Declaration

in relation to Regulation (EU) 2023/607 amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	GCMEDICA ENTERPRISE LTD. (WUXI)
Manufacturer address	Loujin Industrial Park, Shuofang, Wuxi, 214143 Jiangsu, China
Single Registration Number (SRN)	CN-MF-000008756

Authorised Representative name	Kingsmead Service B.V.
Authorised Representative	Zonnehof 36, 2632 BE, Nootdrop, Netherland
Single Registration Number (SRN)	NL-AR-000002066

Notified body name	TÜV Rheinland LGA Products GmbH
Notified body number	0197
Directive Certificate number(s) to which this confirmation is made	DD 60138811 0001
Original expiry date as indicated on the Directive Certificate prior to the extension of the validity	07/02/2024
End date of extended validity/transition period	31/12/2028

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021 and have not been withdrawn afterwards.

  Choose applicable statements:

  ☑Expired/expires *after* 20 March 2023:

  ☑Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its/their substitute(s) and signed written agreement(s) is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

  ☐We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

Choose one applicable statement:

☐A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.
☑A QMS in accordance with Article 10(9) MDR is in place.
☐A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the MDD.
- There are no significant changes in the design and intended purpose.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Name: Adam Jiang	Signature: Adam Jiang 数字签名者：Adam Jiang 日期：2023.09.14 15:32:09 +08'00'
Title: Quality Manager	Date: 14/09/2023

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device(s)[3] (e.g., device name, family/group name device model or catalogue number)	**Directive Certificate number(s) to which this confirmation is made**	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity**	**Notified Body name and number that issued the Directive Certificate**	**Notified Body name and number where the MDR application was lodged/contract signed**	**End date of extended validity / transition period**
Heparin Caps	DD 601388110001	07/02/2024	TÜV Rheinland LGA Products GmbH, 0197	TÜV Rheinland LGA Products GmbH，0197	31/12/2028
Stoppers					
Extension Tubes with 3 Way Stopcock					
Infusion Sets / Infusion Sets with Burette					
Transfusion Sets / Transfusion Sets with Burette					
Endotracheal Tubes/Reinforced Endotracheal Tubes					
Tracheotomy Tubes					
Vaginal Speculums					
Magnetic Drapes for Metal Surgical Device Collection					
Nasal Oxygen Cannula					
Oxygen Masks					
Non-Rebreath Masks					
Aerosol Masks with Nebulizer					
Multi-vent Masks / Venturi Masks					
Tracheostomy Masks					
Capnography Masks					
Capnography Nasal Cannulas					
Suction Catheters					
Nelaton Catheters					
Yankauer Handles					
Suction Connecting Tubes with and without Yankauer					

[3] for devices with AIMDD/MDD certificate(s) the identification should be as in the certificate, and only if the certificate has a generic scope it should be as defined above)

Suture Retrievers	DD 601388110001	07/02/2024	TÜV Rheinland LGA Products GmbH, 0197	TÜV Rheinland LGA Products GmbH，0197	31/12/2028
Decanting Devices/Mixing Cannulas					
Surgical Brushes					
Spigots Catheters					
Flashing Bags for cleaning purpose (Sitz Bath Bags)					
Laryngeal Masks					
Urine Meters					
Urine Bags					
TUR/Bladder Irrigation Sets					
Arthroscopy Irrigation Sets					
Vessel Cannula					
Nasopharyngeal Airways					
Irrigating Syringes					
Ear/Ulcer Syringes					
Mucosal Atomization Devices					
Poole Yankauer					
Disposable Camera Covers/Light Handle Covers					
Bowel Irrigation Systems					
Male Catheter Condoms					
External Catheters					
Basin Drapes					
Rinsing Devices / Blower Devices					
Apron/Drapes					
Scleral Markers					
Waste Collection Bags					
Endoscope Camera Sleeves					
Adaptors/Connectors					
Floor Suction Devices					
Rectal Urodynamic Balloon Catheters					
Needle Counters					
Drainage Tubes					
Dental Irrigation Sets					
ENT-single use suction tubes					
Stylets					
Oropharyngeal Airways					
Stomach Tubes and Feeding Tubes					
Closed Suction Catheters					

Frazier Suction Tubes	DD 601388110001	07/02/2024	TÜV Rheinland LGA Products GmbH，0197	TÜV Rheinland LGA Products GmbH，0197	31/12/2028
Mini Sucker					
HME (Heat and Moisture Exchanger)					
HMEF (Heat and Moisture Exchanger Filters)					
Bacterial/Viral Filters for Breathing or Anesthesia Circuit					
Air Cushion Face Masks					
Oxygen Humidifiers					
Breathing Circuits					
Uterine Aspiration Curettes/Uterine Aspiration Tubes					
Laryngeal Masks					
Suction Specimen Traps					
Insufflator Tubings					
Endoscopic Suction and Irrigation Sets					
Veress Needles					
Irrigation Pump Tubing					