Business Stream Products
Certification Department

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Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

GCMEDICA ENTERPRISE LTD. (WUXI)
Loujin Industrial Park, Shuofang, Wuxi,
214143 Jiangsu,
P.R. China

Contact

Tel. +49 911 655-5225
Mail: medical-products@de.tuv.com

Date March 28, 2024

Notified Body Confirmation Letter
Reference. : 326004435

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 **TÜV Rheinland LGA Products GmbH**, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number **0197** 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 in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

GCMEDICA ENTERPRISE LTD. (WUXI)
Loujin Industrial Park, Shuofang, Wuxi,
214143 Jiangsu,
P.R. China
SRN Number: CN-MF-000008756

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 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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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 March 20, 2023 for the relevant devices.

TÜV Rheinland
LGA Products GmbH

Am Grauen Stein
51105 Köln
Germany

Headquarter

Tillystraße 2
90431 Nuremberg

Phone. +49 911 655 5225
Fax +49 911 655 5226
service@de.tuv.com
www.tuv.com/safety

Board of Management

Dipl.-Ing.
Thomas Weigand, Spokesman

Dipl.-Kfm.
Dr. Jörg Schlösser

Nuremberg HRB 26013
VAT No.: DE 811835490

Chairman of the
Supervisory Board

Dr.-Ing. Michael Fübi

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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:

- May 26, 2026 for Class III custom-made implantable devices
- December 31, 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)
- December 31, 2028 for other Class IIb devices, Class IIa, Class I devices placed on the market in sterile condition or have a measuring function
- December 31, 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

Fuxiu Sheng
Certification body

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 Transfusion Tube Basic UDI-DI code: **697450061SU0503001Y9A**	Class IIa	Transfusion Sets/Transfusion Sets with Burette	DD 60138811 0001 #0197

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 Yankauer Handle Basic UDI-DI code: **697450061OP0703001Y35**	Class IIa	Yankauer Handles; Mini Sucker; Poole Yankauer	DD 60138811 0001 #0197
Sterile Yankauer Handle Basic UDI-DI code: **697450061OP0703002Y38**	Class IIa	Yankauer Handles; Mini Sucker; Poole Yankauer	DD 60138811 0001 #0197
Sterile Yankauer Handle Basic UDI-DI code: **697450061OP0704001Y3G**	Class IIa	Yankauer Handles; Mini Sucker; Poole Yankauer	DD 60138811 0001 #0197
Sterile Yankauer Handle Basic UDI-DI code: **697450061OP0704002Y3K**	Class IIa	Yankauer Handles; Mini Sucker; Poole Yankauer	DD 60138811 0001 #0197

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 Yankauer Handle Basic UDI-DI code: **697450061OP0702001Y2S**	Class IIa	Yankauer Handles; Mini Sucker; Poole Yankauer	DD 60138811 0001 #0197
Sterile Yankauer Handle Basic UDI-DI code: **697450061OP0702002Y2V**	Class IIa	Yankauer Handles; Mini Sucker; Poole Yankauer	DD 60138811 0001 #0197
Sterile Yankauer Handle Basic UDI-DI code: **697450061OP0702003Y2Y**	Class IIa	Yankauer Handles; Mini Sucker; Poole Yankauer	DD 60138811 0001 #0197
Sterile Yankauer Handle Basic UDI-DI code: **697450061OP0702004Y33**	Class IIa	Yankauer Handles; Mini Sucker; Poole Yankauer	DD 60138811 0001 #0197

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 Yankauer Handle Basic UDI-DI code: **697450061OP0702005Y36**	Class IIa	Yankauer Handles; Mini Sucker; Poole Yankauer	DD 60138811 0001 #0197
Sterile Yankauer Handle Basic UDI-DI code: **697450061OP0702006Y39**	Class IIa	Yankauer Handles; Mini Sucker; Poole Yankauer	DD 60138811 0001 #0197
Sterile Yankauer Handle Basic UDI-DI code: **697450061OP0702007Y3C**	Class IIa	Yankauer Handles; Mini Sucker; Poole Yankauer	DD 60138811 0001 #0197
Sterile Yankauer Handle Basic UDI-DI code: **697450061OP0702008Y3F**	Class IIa	Yankauer Handles; Mini Sucker; Poole Yankauer	DD 60138811 0001 #0197

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 Yankauer Handle Basic UDI-DI code: **697450061OP0702009Y3J**	Class IIa	Yankauer Handles; Mini Sucker; Poole Yankauer	DD 60138811 0001 #0197
Sterile Yankauer Handle Basic UDI-DI code: **697450061OP0705001Y3T**	Class IIa	Yankauer Handles; Mini Sucker; Poole Yankauer	DD 60138811 0001 #0197
Sterile Insufflation Tubing Basic UDI-DI code: 697450061OP0202001YY2	Class IIa	Insufflator Tubings	DD 60138811 0001 #0197
Sterile Closed Suction Catheter Basic UDI-DI code: 697450061BR0303001YNK	Class IIa	Closed Suction Catheters	DD 60138811 0001 #0197

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 Closed Suction Catheter Basic UDI-DI code: **697450061BR0303002YNN**	Class IIa	Closed Suction Catheters	DD 60138811 0001 #0197
Sterile Suction Connecting Tube Basic UDI-DI code: **697450061OP0701002Y2J**	Class Is	Suction Connecting Tubes with and without Yankauer	DD 60138811 0001 #0197
Sterile Suction Connecting Tube Basic UDI-DI code: **697450061OP0701003Y2M**	Class Is	Suction Connecting Tubes with and without Yankauer	DD 60138811 0001 #0197
Sterile Heparin Cap Basic UDI-DI code: **697450061SU0507001YAN**	Class Is	Heparin Caps	DD 60138811 0001 #0197

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 Endoscopic Irrigation Tubing Basic UDI-DI code: **697450061OP0402001YZ4**	Class IIa	Irrigation Pump Tubing	DD 60138811 0001 #0197
Sterile Suction Catheter Basic UDI-DI code: **697450061BR0401001YNE**	Class IIa	Suction Catheters	DD 60138811 0001 #0197
Sterile Feeding Tube Basic UDI-DI code: **697450061SU0704001YAP**	Class IIa	Stomach Tubes and Feeding Tubes	DD 60138811 0001 #0197
Sterile Laparoscopic Suction and Irrigation Set Basic UDI-DI code: **697450061OP0201001YXP**	Class IIa	Endoscopic Suction and Irrigation Sets	DD 60138811 0001 #0197

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 Laparoscopic Suction and Irrigation Set Basic UDI-DI code: **697450061OP0201002YXS**	Class IIa	Endoscopic Suction and Irrigation Sets	DD 60138811 0001 #0197
Sterile Laparoscopic Suction and Irrigation Set Basic UDI-DI code: **697450061OP0201003YXV**	Class IIa	Endoscopic Suction and Irrigation Sets	DD 60138811 0001 #0197
Sterile Uterine Aspiration Curette Basic UDI-DI code: **697450061GP0102001YQ9**	Class IIa	Uterine Aspiration Curettes/Uterine Aspiration Tubes	DD 60138811 0001 #0197
Sterile Uterine Aspiration Curette Basic UDI-DI code: **697450061GP0102002YQC**	Class IIa	Uterine Aspiration Curettes/Uterine Aspiration Tubes	DD 60138811 0001 #0197

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 Uterine Aspiration Tube Basic UDI-DI code: **697450061GP0103001YQL**	Class Is	Uterine Aspiration Curettes/Uterine Aspiration Tubes	DD 60138811 0001 #0197
Sterile Uterine Aspiration Tube Basic UDI-DI code: **697450061GP0103002YQP**	Class Is	Uterine Aspiration Curettes/Uterine Aspiration Tubes	DD 60138811 0001 #0197
Sterile Uterine Aspiration Tube Basic UDI-DI code: **697450061GP0103003YQS**	Class Is	Uterine Aspiration Curettes/Uterine Aspiration Tubes	DD 60138811 0001 #0197
Sterile Mucus Specimen Trap Basic UDI-DI code: **697450061BR0402001YNR**	Class IIa	Suction Specimen Traps	DD 60138811 0001 #0197

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 Arthroscopy Irrigation Set Basic UDI-DI code: **697450061OP0102001YXH**	Class IIa	Arthroscopy Irrigation Sets	DD 60138811 0001 #0197
Sterile Bladder Irrigation Set Basic UDI-DI code: **697450061OP0101001YX6**	Class Is	TUR/Bladder Irrigation Sets	DD 60138811 0001 #0197
Sterile Bladder Irrigation Set Basic UDI-DI code: **697450061OP0101002YX9**	Class Is	TUR/Bladder Irrigation Sets	DD 60138811 0001 #0197
Sterile Bladder Irrigation Set Basic UDI-DI code: **697450061OP0101003YXC**	Class Is	TUR/Bladder Irrigation Sets	DD 60138811 0001 #0197

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 Bladder Irrigation Set Basic UDI-DI code: **697450061OP0101004YXF**	Class Is	TUR/Bladder Irrigation Sets	DD 60138811 0001 #0197
Sterile Bowel Irrigation Set Basic UDI-DI code: **697450061SU0202001Y7C**	Class Is	Bowel Irrigation Systems	DD 60138811 0001 #0197
Sterile Decanting Device Basic UDI-DI code: **697450061SU0103001Y76**	Class Is	Decanting Devices/Mixing Cannulas	DD 60138811 0001 #0197
Sterile Mixing Cannula Basic UDI-DI code: **697450061SU0108001Y8V**	Class Is	Decanting Devices/Mixing Cannulas	DD 60138811 0001 #0197

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 ENT Suction Tube Basic UDI-DI code: **697450061OP0703004Y3E**	Class IIa	ENT-single use suction tubes	DD 60138811 0001 #0197
Sterile Veress Needle Basic UDI-DI code: **697450061OP0203001YYD**	Class IIa	Veress Needles	DD 60138811 0001 #0197
Sterile Suction Connecting Tube with Yankauer Handle Basic UDI-DI code: 697450061OP0701001Y2F	Class IIa	Suction Connecting Tubes with and without Yankauer	DD 60138811 0001 #0197
Sterile HME/HMEF(Heat and Moisture Exchanger/Heat and Moisture Exchanger Filter) Basic UDI-DI code: 697450061BR0301001YMV	Class IIa	HME (Heat and Moisture Exchanger); HMEF (Heat and Moisture Exchanger Filters)	DD 60138811 0001 #0197

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 HME/HMEF(Heat and Moisture Exchanger/Heat and Moisture Exchanger Filter) Basic UDI-DI code: **697450061BR0301002YMY**	Class IIa	HME (Heat and Moisture Exchanger); HMEF (Heat and Moisture Exchanger Filters)	DD 60138811 0001 #0197
Non Sterile Nasal Oxygen Cannula Basic UDI-DI code: **697450061BR0102001NLG**	Class IIa	Nasal Oxygen Cannula (Nasal Pressure Cannula)	DD 60138811 0001 #0197
Non Sterile Oxygen Mask Basic UDI-DI code: **697450061BR0103001NLT**	Class IIa	Oxygen Masks	DD 60138811 0001 #0197
Non Sterile Non-Rebreath Mask Basic UDI-DI code: **697450061BR0109001NNV**	Class IIa	Non-Rebreath Masks	DD 60138811 0001 #0197

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**
Non Sterile Aerosol Mask with Nebulizer Basic UDI-DI code: **697450061BR0108001NNJ**	Class IIa	Aerosol Masks with Nebulizer	DD 60138811 0001 #0197
Non Sterile Venturi Mask Basic UDI-DI code: **697450061BR0107001NN7**	Class IIa	Multi-vent Masks / Venturi Masks	DD 60138811 0001 #0197
Non Sterile Venturi Mask Basic UDI-DI code: **697450061BR0107002NNA**	Class IIa	Multi-vent Masks / Venturi Masks	DD 60138811 0001 #0197
Non Sterile Tracheostomy Mask Basic UDI-DI code: **697450061BR0104001NM6**	Class IIa	Tracheostomy Masks	DD 60138811 0001 #0197

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**
Non Sterile Oxygen Humidifier Basic UDI-DI code: **697450061BR0102002NLK**	Class IIa	Oxygen Humidifiers	DD 60138811 0001 #0197
Non Sterile Capnography Mask Basic UDI-DI code: **697450061BR0105001NMH**	Class IIa	Capnography Masks	DD 60138811 0001 #0197
Non Sterile Capnography Nasal Cannula Basic UDI-DI code: **697450061BR0102003NLN**	Class IIa	Capnography Nasal Cannulas	DD 60138811 0001 #0197
Sterile Vaginal Speculum Basic UDI-DI code: 697450061GP0101001YPW	Class Is	Vaginal Speculums	DD 60138811 0001 #0197

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 Suture Retriever Basic UDI-DI code: **697450061OP0501001YZA**	Class IIa	Suture Retrievers	DD 60138811 0001 #0197
Sterile Catheter Spigot Basic UDI-DI code: **697450061DF0101001YDZ**	Class Is	Spigots Catheters; Stoppers	DD 60138811 0001 #0197
Sterile Urine Bag Basic UDI-DI code: **697450061UR0203001Y7C**	Class Is	Urine Bags	DD 60138811 0001 #0197
Sterile Surgical Brush Basic UDI-DI code: **697450061SU0603001Y9T**	Class Is	Surgical Brushes	DD 60138811 0001 #0197

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 Urethral Catheter Basic UDI-DI code: **697450061UR0101001Y65**	Class IIa	Nelaton Catheters	DD 60138811 0001 #0197
Sterile Irrigating Syringe Basic UDI-DI code: **697450061OP0105001YYJ**	Class Is	Irrigating Syringes	DD 60138811 0001 #0197
Sterile Ear/Ucler Syringe Basic UDI-DI code: **697450061GP0201001YQF**	Class Is	Ear/Ulcer Syringes	DD 60138811 0001 #0197
Sterile Mucosal Atomization Device Basic UDI-DI code: **697450061SU0106001Y87**	Class Is	Mucosal Atomization Devices	DD 60138811 0001 #0197

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 Vessel Cannula Basic UDI-DI code: **697450061OP0801001Y2Y**	Class IIa	Vessel Cannula	DD 60138811 0001 #0197
Sterile Camera Cover Basic UDI-DI code: **697450061OP0604001Y2X**	Class Is	Disposable Camera Covers/Light Handle Covers	DD 60138811 0001 #0197
Sterile Light Handle Cover Basic UDI-DI code: **697450061OP0602001Y29**	Class Is	Disposable Camera Covers/Light Handle Covers	DD 60138811 0001 #0197
Sterile Basin Drape Basic UDI-DI code: **697450061OP0302001YYK**	Class Is	Basin Drapes	DD 60138811 0001 #0197

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 Rinsing/Blower Device Basic UDI-DI code: **697450061OP0401001YYR**	Class IIa	Rinsing Devices / Blower Devices	DD 60138811 0001 #0197
Sterile Apron Basic UDI-DI code: **697450061EP0103001YNS**	Class Is	Apron/Drapes	DD 60138811 0001 #0197
Sterile Adaptor/Connector Basic UDI-DI code: **697450061DF0101002YE4**	Class Is	Adaptors/Connectors	DD 60138811 0001 #0197
Sterile Scleral Marker Basic UDI-DI code: **697450061SU0302001Y7V**	Class Is	Scleral Markers	DD 60138811 0001 #0197

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 Camera Sleeve Basic UDI-DI code: **697450061OP0404001YZS**	Class Is	Endoscope Camera Sleeves	DD 60138811 0001 #0197
Sterile Endotracheal Tube Introducer Basic UDI-DI code: **697450061BR0205001YNQ**	Class Is	Stylets	DD 60138811 0001 #0197
Sterile Dental Irrigation Set Basic UDI-DI code: **697450061OP0103001YXU**	Class Is	Dental Irrigation Sets	DD 60138811 0001 #0197
Sterile Oropharyngel Airway Basic UDI-DI code: **697450061BR0202001YMP**	Class IIa	Oropharyngeal Airways	DD 60138811 0001 #0197

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 Nasopharyngeal Airway Basic UDI-DI code: **697450061BR0201001YMC**	Class IIa	Nasopharyngeal Airways	DD 60138811 0001 #0197
Sterile Extension Tube Basic UDI-DI code: **697450061BR0304001YNW**	Class Is	Extension Tubes with 3 Way Stopcock	DD 60138811 0001 #0197
Sterile Extension Tube Basic UDI-DI code: **697450061BR0304002YNZ**	Class Is	Extension Tubes with 3 Way Stopcock	DD 60138811 0001 #0197
Sterile Cuffed Endotracheal Tube Basic UDI-DI code: **697450061BR0203001YN2**	Class IIa	Endotracheal Tubes/Reinforced Endotracheal Tubes	DD 60138811 0001 #0197

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 Cuffed Endotracheal Tube Basic UDI-DI code: **697450061BR0203002YN5**	Class IIa	Endotracheal Tubes/Reinforced Endotracheal Tubes	DD 60138811 0001 #0197
Sterile Uncuffed Endotracheal Tube Basic UDI-DI code: **697450061BR0203003YN8**	Class IIa	Endotracheal Tubes/Reinforced Endotracheal Tubes	DD 60138811 0001 #0197
Sterile Uncuffed Endotracheal Tube Basic UDI-DI code: **697450061BR0203004YNB**	Class IIa	Endotracheal Tubes/Reinforced Endotracheal Tubes	DD 60138811 0001 #0197
Sterile Uncuffed Tracheostmy Tube Basic UDI-DI code: **697450061BR0203006YNH**	Class IIa	Tracheotomy Tubes	DD 60138811 0001 #0197

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 Cuffed Tracheostmy Tube Basic UDI-DI code: **697450061BR0203005YNE**	Class IIa	Tracheotomy Tubes	DD 60138811 0001 #0197
Sterile Laryngectomy Mask Basic UDI-DI code: **697450061BR0204001YND**	Class IIa	Laryngeal Masks	DD 60138811 0001 #0197
Sterile Drape Basic UDI-DI code: **697450061SU0206001Y8Q**	Class Is	Apron/Drapes	DD 60138811 0001 #0197
Sterile Urine Meter Basic UDI-DI code: **697450061UR0203002Y7F**	Class Im	Urine Meters	DD 60138811 0001 #0197

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 Urine Meter Basic UDI-DI code: **697450061UR0203002Y7F**	Class Is	Urine Meters	DD 60138811 0001 #0197
Sterile Male External Catheter Basic UDI-DI code: **697450061UR0102001Y6G**	Class Is	External Catheters; Male Catheter Condoms	DD 60138811 0001 #0197
Sterile Waste Collection Bag Basic UDI-DI code: **697450061OP0307001Y2D**	Class Is	Waste Collection Bags	DD 60138811 0001 #0197
Sterile Floor Suction Device Basic UDI-DI code: **697450061OP0307002Y2G**	Class Is	Floor Suction Devices	DD 60138811 0001 #0197

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 Rectal Tube Basic UDI-DI code: **697450061SU0208001Y9E**	Class Is	Rectal Urodynamic Balloon Catheters	DD 60138811 0001 #0197
Sterile Stomach Tube Basic UDI-DI code: **697450061SU0701001Y9N**	Class IIa	Stomach Tubes and Feeding Tubes	DD 60138811 0001 #0197
Sterile Drainage Tube Basic UDI-DI code: **697450061OP0901001Y3H**	Class IIa	Drainage Tubes	DD 60138811 0001 #0197
Sterile Infusion Set Basic UDI-DI code: **697450061SU0502001Y8X**	Class Is	Infusion Sets / Infusion Sets with Burette	DD 60138811 0001 #0197

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 Frazier Suction Tube Basic UDI-DI code: **697450061OP0703003Y3B**	Class IIa	Frazier Suction Tubes	DD 60138811 0001 #0197
Sterile Bacterial/Viral Filter Basic UDI-DI code: **697450061BR0301003YN3**	Class IIa	Bacterial/Viral Filters for Breathing or Anesthesia Circuit	DD 60138811 0001 #0197
Non Sterile Anesthesia Mask Basic UDI-DI code: **697450061BR0305001NNK**	Class IIa	Air Cushion Face Masks	DD 60138811 0001 #0197
Non Sterile Breathing Circuit Basic UDI-DI code: **697450061BR0309001NPX**	Class IIa	Breathing Circuits	DD 60138811 0001 #0197

Table 2: Devices covered by this letter and for which the NB is <u>NOT</u> 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	NB internal reference traceable to each version of the letter	Action
2024/03/28	326004435	Initial issue

Manufacturer's Declaration

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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

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[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 to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made by us to a notified body for the devices listed in the attached schedule and signed written agreement is in place in accordance with Section 4.3, second subparagraph of Annex VII MDR.

  ☐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:
Title: Quality Manager	Date: 06/02/2024

[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 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	DD 601388110001	07/02/2024	TÜV Rheinland LGA Products GmbH，0197	TÜV Rheinland LGA Products GmbH，0197	31/12/2028

[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)

Suction Connecting Tubes with and without Yankauer	DD 601388110001	07/02/2024	TÜV Rheinland LGA Products GmbH，0197	TÜV Rheinland LGA Products GmbH，0197	31/12/2028
Suture Retrievers					
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					

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Stomach Tubes and Feeding Tubes	DD 601388110001	07/02/2024	TÜV Rheinland LGA Products GmbH，0197	TÜV Rheinland LGA Products GmbH，0197	31/12/2028
Closed Suction Catheters					
Frazier Suction Tubes					
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					
Suction Specimen Traps					
Insufflator Tubings					
Endoscopic Suction and Irrigation Sets					
Veress Needles					
Irrigation Pump Tubing					

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EC Certificate

Directive 93/42/EEC Annex V
Production Quality Assurance
Medical Devices

Registration No.: DD 60138811 0001

Report No.: 15065307 008

Manufacturer:
GCMEDICA ENTERPRISE LTD.(WUXI)
Loujin Industrial Park, Shuofang
Wuxi
214143 Jiangsu
China

Products:
Medical Devices

(see attachment for products included)

Replaces Approval, Registration No.: DD 60130545 0001

Expiry Date: 2024-02-07

The Notified Body hereby declares that the requirements of Annex V of the directive 93/42/EEC have been met for the listed products. The above named manufacturer has established and applies a quality assurance system, which is subject to periodic surveillance, defined by Annex V, section 4 of the aforementioned directive. For placing on the market of class IIb and class III devices covered by this certificate an EC type-examination certificate according to Annex III is required.

Effective Date: 2019-05-24

Date: 2019-05-24

Notified Body

TÜV Rheinland LGA Products GmbH Zertifizierungsstelle

Fuxiu Sheng

TÜV Rheinland LGA Products GmbH - Tillystraße 2 - 90431 Nürnberg
TÜV Rheinland LGA Products GmbH is a Notified Body according to Directive 93/42/EEC concerning medical devices with the identification number 0197.

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TÜVRheinland®

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60138811 0001
Report No.: 15065307 008

Manufacturer:
GCMEDICA ENTERPRISE LTD.(WUXI)
Loujin Industrial Park, Shuofang
Wuxi
214143 Jiangsu
China

Products:

Closed Suction Catheters, Infusion Sets / Infusion Sets with Burette, Transfusion Sets / Transfusion Sets with Burette, Extension Tubes with 3 Way Stopcock, Heparin Caps, Frazier Suction Tubes, Mini Sucker, Suction Connecting Tubes with and without Yankauer, Nasal Oxygen Cannula, Oxygen Masks, Non-Rebreath Masks, Aerosol Masks with Nebulizer, Multi-vent Masks/Venturi Masks, Tracheostomy Masks, Air Cushion Face Masks, Suction Catheters, Stomach Tubes and Feeding Tubes, Endotracheal Tubes / Reinforced Endotracheal Tubes, Tracheotomy Tubes, Oxygen Humidifiers, Breathing Circuits, HMEF(Heat and Moisture Exchanger Filters), HME(Heat and Moisture Exchanger), Bacterial/Viral Filters for Breathing or Anesthesia Circuit, Endoscopic Suction and Irrigation Sets, Veress Needles, Laryngeal Masks, Uterine Aspiration Curettes / Uterine Aspiration Tubes, Insufflator Tubings, Suction Specimen Traps, Yankauer Handles, Poole Yankauer, Capnography Masks, Capnography Nasal Cannulas, Irrigation Pump Tubings;

Notified Body

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

Date: 2019-05-24

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Doc. 2/2, Rev. 0

TÜV Rheinland
LGA Products GmbH
Tillystraße 2, 90431 Nürnberg

Attachment to Certificate
Registration No.: DD 60138811 0001
Report No.: 15065307 008

Manufacturer:
GCMEDICA ENTERPRISE LTD.(WUXI)
Loujin Industrial Park, Shuofang
Wuxi
214143 Jiangsu
China

Aspects of manufacture concerned with securing and maintaining sterile conditions:

Magnetic Drapes for Metal Surgical Device Collection, Suture Retrievers, Decanting Devices/Mixing Cannulas, Spigots Catheters, Stoppers, Flashing Bags for cleaning purpose (Sitz Bath Bags), Enema Bags, Urine Meters, Urine Bags, Oropharyngeal Airways, Nasopharyngeal Airways, Surgical Brushes, Vaginal Speculums, Nelaton Catheters, Irrigating Syringes, Ear/Ulcer Syringes, Mucosal Atomization Devices, TUR/Bladder Irrigation Sets, Arthroscopy Irrigation Sets, Vessel Cannula, Bowel Irrigation Systems, Disposable Camera Covers/Light Handle Covers, Basin Drapes, Rinsing Devices/Blower Devices, Apron/Drapes, Adaptors/Connectors, Floor Suction Devices, Male Catheter Condoms, Rectal Urodynamic Balloon Catheters, External Catheters, Waste Collection Bags, Scleral Markers, Endoscope Camera Sleeves, Needle Counters, Stylets, Drainage Tubes, Dental Irrigation Sets, ENT-single use suction tubes

Notified Body

TÜVRheinland LGA Products GmbH Zertifizierungsstelle

Date: 2019-05-24

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