

TÜV Rheinland LGA Products GmbH • 51105 Köln

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213116 Changzhou, Jiangsu,
P.R. China

Contact

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Date April 23, 2024

Notified Body Confirmation Letter

Reference. : 326012944

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:

Changzhou Huankang Medical Device Co., Ltd.
22 Changhe Road, Sanhekou, Zhenglu,
213116 Changzhou, Jiangsu,
P.R. China
SRN Number (if available): CN-MF-000009030

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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

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Chairman of the
Supervisory Board

Dr.-Ing. Michael Fübi

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
Suction Catheter Basic UDIDI: 69459346HKC0101NQ	Class IIa	N/A	Certificate #DD 60149774 0001 NB #0197
Suction Catheter Basic UDIDI: 69459346HKC0102NS	Class IIa	N/A	Certificate #DD 60149774 0001 NB #0197
Endotracheal Tube Basic UDIDI: 69459346HKE01T7	Class IIa	N/A	Certificate #DD 60149774 0001 NB #0197
Endotracheal Tube Basic UDIDI: 69459346HKE03TB	Class IIa	N/A	Certificate #DD 60149774 0001 NB #0197
Endotracheal Tube Basic UDIDI: 69459346HKE02T9	Class IIa	N/A	Certificate #DD 60149774 0001 NB #0197
Endotracheal Tube Basic UDIDI: 69459346HKE04TD	Class IIa	N/A	Certificate #DD 60149774 0001 NB #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
Nasal Oxygen Cannula Basic UDIDI: 69459346HKC08TB	Class IIa	N/A	Certificate #DD 60149774 0001 NB #0197
Oxygen Mask Basic UDIDI: 69459346HKD01T2	Class IIa	N/A	Certificate #DD 60149774 0001 NB #0197
Stomach Tube Basic UDIDI: 69459346HKC0301P2	Class IIa	N/A	Certificate #DD 60149774 0001 NB #0197
Stomach Tube Basic UDIDI: 69459346HKC0302P4	Class IIa	N/A	Certificate #DD 60149774 0001 NB #0197
Feeding Tube Basic UDIDI: 69459346HKC04T3	Class IIa	N/A	Certificate #DD 60149774 0001 NB #0197
Disposable Trocar Basic UDIDI: 69459346HKM0101S6	Class IIa	N/A	Certificate #DD 60149774 0001 NB #0197
Disposable Trocar Basic UDIDI: 69459346HKM0102S8	Class IIa	N/A	Certificate #DD 60149774 0001 NB #0197
Disposable Trocar Basic UDIDI: 69459346HKM0103SA	Class IIa	N/A	Certificate #DD 60149774 0001 NB #0197
Disposable Trocar Basic UDIDI: 69459346HKM0104SC	Class IIa	N/A	Certificate #DD 60149774 0001 NB #0197
Veress Needle Basic UDIDI: 69459346HKM02UH	Class IIa	Disposable Veress Needles	Certificate #DD 60149774 0001 NB #0197
Endoscopic Retrieval Bag Basic UDIDI: 69459346HKM0301SG	Class IIa	Disposable Endoscopic Retrieval Bags	Certificate #DD 60149774 0001 NB #0197
Endoscopic Retrieval Bag Basic UDIDI: 69459346HKM0302SJ	Class IIa	Disposable Endoscopic Retrieval Bags	Certificate #DD 60149774 0001 NB #0197
Endoscopic Retrieval Bag Basic UDIDI:	Class IIa	Disposable Endoscopic Retrieval Bags	Certificate #DD 60149774 0001 NB #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
69459346HKM0303SL			
Endoscopic Retrieval Bag Basic UDIDI: 69459346HKM0304SN	Class IIa	Disposable Endoscopic Retrieval Bags	Certificate #DD 60149774 0001 NB #0197
Endoscopic Retrieval Bag Basic UDIDI: 69459346HKM0305SQ	Class IIa	Disposable Endoscopic Retrieval Bags	Certificate #DD 60149774 0001 NB #0197
Endoscopic Retrieval Bag Basic UDIDI: 69459346HKM0306SS	Class IIa	Disposable Endoscopic Retrieval Bags	Certificate #DD 60149774 0001 NB #0197
Vaginal Speculum Basic UDIDI: 69459346HKA04SR	Class I devices placed on the market in sterile condition	Disposable Vaginal Speculums	Certificate #DD 60149774 0001 NB #0197
Vaginal Speculum Basic UDIDI: 69459346HKA05ST	Class I devices placed on the market in sterile condition	Disposable Vaginal Speculums	Certificate #DD 60149774 0001 NB #0197
Vaginal Speculum Basic UDIDI: 69459346HKA06SV	Class I devices placed on the market in sterile condition	Disposable Vaginal Speculums	Certificate #DD 60149774 0001 NB #0197
Nelaton Catheter Basic UDIDI: 69459346HKC02NRT	Class I devices placed on the market in sterile condition	N/A	Certificate #DD 60149774 0001 NB #0197
Nelaton Catheter Basic UDIDI: 69459346HKC02HRF	Class I devices placed on the market in sterile condition	N/A	Certificate #DD 60149774 0001 NB #0197
Urine Drainage Bag Basic UDIDI: 69459346HKB01SQ	Class I devices placed on the market in sterile condition	Disposable Urine Drainage Bags	Certificate #DD 60149774 0001 NB #0197
Urine Drainage Bag Basic UDIDI: 69459346HKB02SS	Class I devices placed on the market in sterile condition	Disposable Urine Drainage Bags	Certificate #DD 60149774 0001 NB #0197
Urine Drainage Bag Basic UDIDI: 69459346HKB03SU	Class I devices placed on the market in sterile condition	Disposable Urine Drainage Bags	Certificate #DD 60149774 0001 NB #0197
Urine Drainage Bag Basic UDIDI: 69459346HKB04SW	Class I devices placed on the market in sterile condition	Disposable Urine Drainage Bags	Certificate #DD 60149774 0001 NB #0197
Urine Drainage Bag	Class I devices placed on the	Disposable Urine Drainage Bags	Certificate #DD 60149774 0001

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
Basic UDIDI: 69459346HKB05SY Urine Drainage Bag	market in sterile condition		NB #0197
Basic UDIDI: 69459346HKB06T2 Urine Drainage Bag	Class I devices placed on the market in sterile condition	Disposable Urine Drainage Bags	Certificate #DD 60149774 0001 NB #0197
Basic UDIDI: 69459346HKB08T6 Urine Drainage Bag	Class I devices placed on the market in sterile condition	Disposable Urine Drainage Bags	Certificate #DD 60149774 0001 NB #0197
Basic UDIDI: 69459346HKB09T8 Urine Drainage Bag	Class I devices placed on the market in sterile condition	Disposable Urine Drainage Bags	Certificate #DD 60149774 0001 NB #0197
Basic UDIDI: 69459346HKB10SR Urine Drainage Bag	Class I devices placed on the market in sterile condition	Disposable Urine Drainage Bags	Certificate #DD 60149774 0001 NB #0197
Rectal Tube Basic UDIDI: 69459346HKC05T5	Class I devices placed on the market in sterile condition	N/A	Certificate #DD 60149774 0001 NB #0197
Umbilical Cord Clamp Basic UDIDI: 69459346HKJ04ASQ	Class I devices placed on the market in sterile condition	N/A	Certificate #DD 60149774 0001 NB #0197
Umbilical Cord Clamp Basic UDIDI: 69459346HKJ04BSS	Class I devices placed on the market in sterile condition	N/A	Certificate #DD 60149774 0001 NB #0197
Waste Liquid Suction Bag Basic UDIDI: 69459346HKB11ST	Class I devices placed on the market in sterile condition	Disposable Waste Liquid Suction Bags	Certificate #DD 60149774 0001 NB #0197
Vaginal Applicator Basic UDIDI: 69459346HKI01TT	Class I devices placed on the market in sterile condition	Disposable Vaginal Irrigation Sets	Certificate #DD 60149774 0001 NB #0197
Vomit Bag Basic UDIDI: 69459346HKI05U3	Class I devices placed on the market in sterile condition	N/A	Certificate #DD 60149774 0001 NB #0197
Enema Bag Basic UDIDI: 69459346HKI04TZ	Class I devices placed on the market in sterile condition	N/A	Certificate #DD 60149774 0001 NB #0197
Suction Connecting Tubes with Yankauer Basic UDIDI: 69459346HKC09TD	Class IIa	N/A	Certificate #DD 60149774 0001 NB #0197
Mucus Extractors	Class IIa	N/A	Certificate #DD 60149774 0001

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
Basic UDIDI: 69459346HKC07T9			NB #0197
Disposable Gynecological Kits Basic UDIDI: 69459346HKK01U5	Class IIa	N/A	Certificate #DD 60149774 0001 NB #0197
Disposable Biopsy Forceps Basic UDIDI: 69459346HKF01TC	Class IIa	N/A	Certificate #DD 60149774 0001 NB #0197
Disposable Colostomy Bags Basic UDIDI: 69459346HKL01UA	Class I devices placed on the market in sterile condition	N/A	Certificate #DD 60149774 0001 NB #0197
Medical Brushes Basic UDIDI: 69459346HKJ03U4	Class I devices placed on the market in sterile condition	N/A	Certificate #DD 60149774 0001 NB #0197
Irrigation Syringes Basic UDIDI: 69459346HKI02TV	Class I devices placed on the market in sterile condition	N/A	Certificate #DD 60149774 0001 NB #0197

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
NA	NA	NA	NA

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024-04-23	326012944	Initial issue