Business Stream Products
Certification Department

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LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Roosin Medical Co., Ltd.
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Taizhou City,
225321 Jiangsu,
P.R. China

Contact

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Date May 10, 2024

Notified Body Confirmation Letter
Reference. : 326014718

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:

Roosin Medical Co., Ltd.
No.8 Yuandong Road, Kouan Town, Gaogang,
Taizhou City, 225321 Jiangsu,
P.R. China
SRN Number: CN-MF-000021163

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after May 26, 2021 but before March 20, 2023 without having been withdrawn, this letter also confirms that the manufacturer either signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided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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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**
Relieve Burn Gel Model: Gel type Basic UDI-DI: 69588687CEMDR0010186	Class IIb excluding Class IIb implantable non-WET	Sterile Burn Gels	Certificate # HD 60149016 0001; NB# 0197
Relieve Burn Gel Model: Spray type Basic UDI-DI: 69588687CEMDR0010288	Class IIb excluding Class IIb implantable non-WET	Sterile Burn Gels	Certificate # HD 60149016 0001; NB# 0197
Relieve Burn Gel Model: Dressing type Basic UDI-DI: 69588687CEMDR001038A	Class IIb excluding Class IIb implantable non-WET	Sterile Burn Gels	Certificate # HD 60149016 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**
Calcium alginate wound dressing Basic UDI-DI: 69588687CEMDR004FQ	Class IIb excluding Class IIb implantable non-WET	Hydrophilic-Gel Exudate-Absorbent Dressing	Certificate # HD 60149016 0001; NB# 0197
Foam dressing Model: adhesive Basic-DI-DI: 69588687CEMDR002018B	Class IIa	N/A	Certificate # DD 60149017 0001; NB# 0197
Foam dressing Model: non-adhesive with PU Film Basic-DI-DI: 69588687CEMDR002028D	Class IIa	N/A	Certificate # DD 60149017 0001; NB# 0197
Foam dressing Model: non-adhesive without PU Film Basic-DI-DI: 69588687CEMDR002038F	Class IIa	N/A	Certificate # DD 60149017 0001; NB# 0197
Hydrocolloid Wound Dressing Basic-DI-DI: 69588687CEMDR005FS	Class IIa	N/A	Certificate # DD 60149017 0001; NB# 0197
Wound Hydrogel Dressing Basic-DI-DI: 69588687CEMDR006FU	Class IIa	N/A	Certificate # DD 60149017 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**
Paraffin Gauze Dressing Basic-DI-DI: 69588687CEMDR007FW	Class IIa	Cotton Burn Dressings	Certificate # DD 60149017 0001; NB# 0197
Sterile Dressing Basic-DI-DI: 69588687CEMDR008FY	Class I devices placed on the market in sterile condition	N/A	Certificate # DD 60149017 0001; NB# 0197
Silicone Foam Dressing Basic-DI-DI: 69588687CEMDR012FP	Class IIb excluding Class IIb implantable non-WET	Silicone Foam Dressing (Gamma sterilziation)	Certificate # DD 60149017 0001; NB# 0197
Absorbent Pad Basic UDI-DI: 69588687CEMDR010FK	Class I devices placed on the market in sterile condition	N/A	Certificate # DD 60149017 0001; NB# 0197
Irrigation solution for eye and wound wash Basic UDI-DI: 69588687CEMDR009G2	Class IIa	N/A	Certificate # DD 60149017 0001; NB# 0197
Oil Emusion vaseline Dressing Basic UDI-DI: 69588687CEMDR011FM	Class IIa	N/A	Certificate # DD 60149017 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
N/A	N/A	N/A	N/A

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/03/11	244567187	Initial issue
2024/05/10	326014718	Products addition