爱德欧医疗用品有限公司
IDION MEDICAL CO.,LTD
TEL:+86-572-8086557 FAX:+86-572-8088777
地址：浙江省德清县武康镇曲园北路 519 号
Add: Quyuan Road 519,Industry Area,Wukang Town,Deqing,Zhejiang,China

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 and in vitro diagnostic medical devices, in particular with respect to

- the validity of certificates issued under Council Directive 90/385/EEC on Active Implantable Medical Devices (AIMDD) or 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	Idion Medical Co.,Ltd.
Manufacturer address and contact details	No.519 Quyuan North Road,Wukang Town,Deqing,Huzhou,Zhejiang province 313200 China
Single Registration Number (SRN) (if available)	CN-MF-000017964

Authorised Representative name (if applicable)	Riomavix S.L.
Authorised Representative address and contact details	Calle de Almansa 55,1D,Madrid 28039 Spain
Single Registration Number (SRN) (if available)	ES-AR-000001202

Notified body name (if applicable)	TUV Rheinland LGA Products GmbH
Notified body number (if applicable)	CE 0197
Directive Certificate number(s) to which this confirmation is made (if applicable)	DD 601500410001 MDR (EU) 2017/745 Annex IX Chapter I

[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.

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Original expiry date as indicated on the Directive Certificate prior to the extension of the validity (if *applicable*)	May 26, 2024
End date of extended validity/transition period	December 31, 2028
Extension Letter Reference	326011968

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 *before* 20 March 2023:

  ☐ Before the original date of expiry as indicated on the Directive Certificate(s), we and the notified body have signed written agreement(s) in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment(s) in respect of the device(s) covered by the expired certificate(s) or in respect of a device(s) intended to substitute that/those device(s), or

  ☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request), or

  ☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

  Choose one of the following statements only if a derogation per Article 59(1) or a requirement per Article 97(1) has been granted by a Competent Authority:

[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

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.

☑ Expired/expires *after* 20 March 2023:

Choose one applicable statement:

☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or 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.

➢ **Upclassified devices**

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:

Choose one applicable statement:

☑ Formal application(s) to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has/have been made or 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 substitutes 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 AIMDD or MDD.
- There are no significant changes in the design and intended purpose.

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- 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:

Full Company Name	Idion Medical Co.,Ltd.
Location & Date	Deqing, Zhejiang June 9，2026
Signature, Print Name, Title	lily Yao General Manager
Contact Details (at least email)	yll@idion-medical.com

爱德欧医疗用品有限公司
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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** (if applicable)	**Original expiry date as indicated on the Directive Certificate (s) prior to the extension of the validity** (if applicable)	**Notified Body name and number that issued the Directive Certificate** (if applicable)	**Notified Body name and number where the MDR application was lodged/contract signed** (if applicable)	**End date of extended validity / transition period**	**Substitute Device(s)** (if applicable)
Disposable Medical Scissors SCI-01 50014	DD 60150041001 NB#0197	May 26, 2024	TUV Rheinland LGA Products GmbH CE 0197	TUV Rheinland LGA Products GmbH CE 0197	December 31, 2028	
Disposable Medical Scissors SCI-02 50015	DD 60150041001 NB#0197	May 26, 2024	TUV Rheinland LGA Products GmbH CE 0197	TUV Rheinland LGA Products GmbH CE 0197	December 31, 2028	
Disposable Medical Scissors SCI-03 50016	DD 60150041001 NB#0197	May 26, 2024	TUV Rheinland LGA Products GmbH CE 0197	TUV Rheinland LGA Products GmbH CE 0197	December 31, 2028	
Disposable Medical Scissors SCI-04 50017	DD 60150041001 NB#0197	May 26, 2024	TUV Rheinland LGA Products GmbH CE 0197	TUV Rheinland LGA Products GmbH CE 0197	December 31, 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)

Business Stream Products
Certification Department

TÜVRheinland®
LGA
Precisely Right.

TÜV Rheinland LGA Products GmbH • 51105 Köln

Idion Medical Co., Ltd.
Quyuan Road 519, Industry Area, Wukang Town, Deqing,
313200 Zhejiang,
P.R.China

Contact

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

Date May 09, 2024

Notified Body Confirmation Letter
Reference. : 326011968

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:

Idion Medical Co., Ltd.
Quyuan Road 519, Industry Area, Wukang Town, Deqing,
313200 Zhejiang,
P.R.China
SRN Number (if available): CN-MF-000017964

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

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Germany

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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 Gauze Swabs Basic UDI-DI: 697507444IDO001G5	Class Is	N/A	DD 60150041 0001 NB#0197
Medical Non-woven Swabs Basic UDI-DI: 697507444IDO002G7	Class Is	N/A	DD 60150041 0001 NB#0197
Sterile Non-adherent Pads Basic UDI-DI: 697507444IDO003G9	Class Is	N/A	DD 60150041 0001 NB#0197
Sterile First Aid Dressing Bandages Basic UDI-DI: 697507444IDO004GB	Class Is	N/A	DD 60150041 0001 NB#0197
Sterile Vaginal Speculums Basic UDI-DI: 697507444IDO005GD	Class Is	N/A	DD 60150041 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
Medicine Cups Basic UDI-DI: 697507444IDO006GF	Class Im	N/A	DD 60150041 0001 NB#0197
Disposable Medical Scissors Basic UDI-DI: 697507444IDO007GH	Class Is	N/A	DD 60150041 0001 NB#0197
X-ray Detectable Gauze Sponges Basic UDI-DI: 697507444IDO008GK	Class IIa	N/A	DD 60150041 0001 NB#0197
ABD pads Basic UDI-DI: 697507444IDO009GM	Class IIa	N/A	DD 60150041 0001 NB#0197
Sterile cotton Balls Basic UDI-DI: 697507444IDO010G6	Class Is	N/A	DD 60150041 0001 NB#0197
Bowl Liners Basic UDI-DI: 697507444IDO011G8	Class Is	N/A	DD 60150041 0001 NB#0197
Surgical kits Basic UDI-DI: 697507444IDO01201Q4	Class IIa	N/A	DD 60150041 0001 NB#0197
Surgical kits Basic UDI-DI: 697507444IDO01202Q6	Class IIa	N/A	DD 60150041 0001 NB#0197
Surgical kits Basic UDI-DI: 697507444IDO01203Q8	Class IIa	N/A	DD 60150041 0001 NB#0197
Surgical kits Basic UDI-DI: 697507444IDO01204QA	Class IIa	N/A	DD 60150041 0001 NB#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
2024-05-09	326011968	Initial issue