



Dirinco MDD Certificate (expiring 26 May 2024) continue to be valid until 31 December 2028

Subject: To formal communicate that the Dirinco BV CE Certificate under MDD 93/42/EEC expiring 26 MAY 2024 **will remain valid until 31 December 2028** in accordance with Regulation (EU) 2023/607 amending MDR 2017/745.

To whom this letter may concern,

With the publication of the Regulation (EU) 2017/745 (also referred as MDR) in 2017, Dirinco BV initiated the implementation activities in order to prepare the transition to MDR on time. Since early 2021, Dirinco BV started the submission process with its notified body- TÜV Rheinland - to guarantee the MDR certification before May 26th 2024.

Unfortunately, despite all Dirinco BV's efforts to comply with the requested requirements and timelines, we were informed that due to the TÜV Rheinland lack of capacity, the conformity assessment of the Dirinco BV devices will not happen before 26 May 2024, the date on which the current MDD certificate issued in accordance with Directive 93/42/EEC will expire.

Therefore, in order to authorize Dirinco BV to continue placing on the market the devices covered by the expired MDD certificate after May 26th 2024, TÜV Rheinland issued an Agreement as recorded in the Notified Body Confirmation Letter on April 29th 2024: Extension of validity of TÜV Rheinland Certification Agreement for continuation of MDD 93/42/EEC surveillance activities, in reference to Regulation (EU) 2023/607 of the European Parliament and of the Council of 15 March 2023 amending Regulation (EU) 2017/745 as regards the transitional provision for certain medical devices.

Please consult the aforementioned Agreement attached to this letter.

The risk of shortages of medical devices for the patients in need of medical care is a matter of concern for Dirinco BV. Although this extension provided by TÜV Rheinland allows Dirinco BV to continue supplying safe and effective CE marked medical devices until December 31th 2028, we expect that this extension should be only of sufficient duration to give TÜV Rheinland the necessary time to carry out the conformity assessments required and issue the MDR certificates as soon as possible.

Sincerely,


Maha Kansel Haimour – General Manager
15th of May 2024

TÜV Rheinland LGA Products GmbH • 51105 Köln

DIRINCO B.V.
Lauwersmeer 9C
5347 JR Oss
Netherlands

Contact

Tel. +49 911 655-5225

Mail: medical-products@de.tuv.com

Date April 29, 2024

Notified Body Confirmation Letter

Reference: DIRIN_MDR Application 2024-03-26; order # 1159091

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:

DIRINCO B.V.
Lauwersmeer 9C
5347 JR Oss
Netherlands
SRN Number (if available): NL-MF-000002150

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

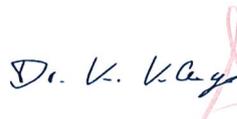
Chairman of the
Supervisory Board

Dr.-Ing. Michael Fübi

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

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 von Karsten Kluge
 Datum: 2024.04.29
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i.V. Dr. Karsten Kluge
 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 |
|---|---|--|--|
| Citra-Lock™ Catheter lock solutions 4% | IIb non-implantable | N/A | HD 60148183 0001 #0197 |
| Citra-Lock™ Catheter lock solutions 30% | IIb non-implantable | N/A | HD 60148183 0001 #0197 |
| Citra-Lock™ Catheter lock solutions 46.7% | IIb non-implantable | N/A | HD 60148183 0001 #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 |
|------------|---|------------------------------------|
| 2024/04/29 | DIRIN_CL607_2024-04-29.pdf | Initial issue |
| YYYY/MM/DD | XXXXXXXXXX | Addition of device XYZ to the list |
| YYYY/MM/DD | XXXXXXXXXX | Removal of device XYZ to the list |