

DEKRA Certification GmbH – Handwerkstraße 15 – D-70565 Stuttgart

JOTEC GmbH
Ms. Dr. Cornelia Kuschel
Lotzenäcker 23
72379 Hechingen
Germany

DEKRA Certification GmbH

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Date 2024-05-17

Subject: Notified Body Confirmation Letter

Our reference: 50736-CL-00, Rev.00

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 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices

Dear Ms. Kuschel

This letter confirms that, DEKRA Certification GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0124 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:

JOTEC GmbH
Lotzenäcker 23
72379 Hechingen
Germany

SRN Number: DE-MF-000005709

The devices covered by the formal application and the written agreement mentioned above are identified in the Tables 1 and 2 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 of the corresponding devices under the applicable Directive MDD. 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 MDD.

In the case of devices covered by certificates issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD certificate expiry; or provided evidence that a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 the 20 Mar 2023 for the relevant devices.

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:

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

Furthermore, DEKRA Certification GmbH confirms that an agreement between JOTEC GmbH and DEKRA Certification GmbH is in place about the surveillance of the products that are covered by the certificate(s) mentioned in table 3 according to Regulation (EU) 2017/745 Article 120.

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 has been published on 20 March 2023 and came into force on the same day. This Regulation 2023/607 has amended MDR 2017/745 to now identify that under certain conditions certificates issued by Notified Bodies, as DEKRA Certification GmbH, in accordance with the MDD 93/42/EEC that were still valid on 26.05.2021 and that have not been withdrawn afterwards shall remain valid after the end of the period indicated on the certificate, see Table 3 under certain conditions. Additionally, should JOTEC GmbH intend to make use of the extension of the validity of the EC-certificates, involvement of DEKRA Certification GmbH for continued surveillance is required.

This Confirmation Letter identifies the products or product groups and EC certificates according to MDD 93/42/EEC (see Table 3) for which JOTEC GmbH intends to make use of the option for extension of the validity of the EC certificates (see Table 3).

If JOTEC GmbH has intentions to make use of the option for extension of the validity of the EC certificates (see Table 3) as detailed in the amendment of the MDR 2017/745 by Regulation (EU) 2023/607,

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

the following conditions have to be met:

- JOTEC GmbH or its Authorized Representative has to ensure that a formal application acc. to the MDR 2017/745 Section 4.3, first subparagraph of Annex VII for the conformity assessment will have been lodged with DEKRA Certification GmbH, latest by 26 May 2024. The application should be placed for the product(s) or groups of products intended to substitute those product(s).
- JOTEC GmbH or its Authorized Representative has to ensure that a written agreement in accordance with the MDR 2017/745 Section 4.3, second subparagraph of Annex VII will have been signed with DEKRA Certification GmbH, latest by 26 September 2024.

Should the MDR application not be lodged and the written agreement not to be signed acc. to the mentioned timelines, the EC certificates mentioned in the Table 3, cannot be considered valid after 26. September 2024.

Validity of this confirmation letter:

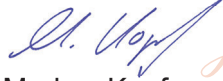
For products included in table 1 and 2:

Until the end of applicable transition timelines specified in Article 120.3c of MDR (as amended by (EU) 2023/607

For products included in table 3:

Until the latest: 2024-09-25.

On behalf of the Notified Body,



Digitally signed by Markus
RAINER Kopf
Date: 2024-05-17 15:46:18+02:00

Markus Kopf
2024/05/17

Enclosures:

Confirmation Letter Annex

Annex to Notified Body Confirmation Letter 50736-CL-00, Rev.00

Table 1

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
E-tegra Stent Graft System	Class III	N/A	Certificates #50736-16-08_Rev0; #DEC50736-23-J1_Rev2; NB #DEKRA Certification GmbH, CE0124
E-liac Stent Graft System	Class IIb implantable non-WET device	N/A	Certificate #50736-16-08_Rev0; NB #DEKRA Certification GmbH, CE0124
FlowLine Bipore Heparin ePTFE Vascular Graft	Class III	N/A	Certificates #50736-16-08_Rev0; #DEC50736-23-C5_Rev0; NB #DEKRA Certification GmbH, CE0124
E-vita OPEN NEO	Class III	N/A	Certificates #50736-16-08_Rev0; #DEC50736-23-M1_Rev0; NB #DEKRA Certification GmbH, CE0124

Textile Vascular Grafts: FlowWeave Bioseal, FlowNit Bioseal	Class III	N/A	Certificates #50736-16-08_Rev0; #DEC50736-53- A6_Rev0; NB #DEKRA Certification GmbH, CE0124
E-xpand Stent Graft Balloon catheter	Class III	N/A	Certificate #50736-16-08_Rev0; NB #DEKRA Certification GmbH, CE0124
E-nside TAAA Multibranched Stent Graft System	Class III	N/A	Certificates #50736-16-08_Rev0; #DEC50736-23- K0_Rev0; NB #DEKRA Certification GmbH, CE0124

Table 2:

Not applicable

Table 3:

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
E-wire Guide Wire	Class III	N/A	Certificate #50736-16-08_Rev0; NB #DEKRA Certification GmbH, CE0124
FlowLine Bipore ePTFE Vascular Graft	Class IIb implantable non- WET device	N/A	Certificate #50736-16-08_Rev0; NB #DEKRA Certification GmbH, CE0124