

TÜV NORD CERT GmbH, Am TÜV 1, 45307 Essen, Germany

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## TÜV NORD CERT GmbH

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TÜV®

Reference	Contact	Direct Dial	Date
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### Notified Body Confirmation Letter

**Reference: EC-Certificate acc. 93/42/EEC Annex II without (4), No.: 44 232 191507,  
35252605**

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 NORD CERT GmbH, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number 0044 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:

Diversey Europe Operations B.V.  
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SRN: NL-MF-000006623

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

On behalf of the Notified Body,

i. V. Kevin Mühlberg  
Head of Project Management  
Medical Devices International  
TÜV NORD CERT GmbH  
Notified Body for Medical Devices

i. A. Bodo Mestmacher  
TIC Manager MDR  
Medical Devices International  
TÜV NORD CERT GmbH  
Notified Body for Medical Devices

**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
<b>Oxivir Excel CE</b>	Class IIa	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232191507
<b>Oxivir Excel</b>	Class IIa	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232191507
<b>Oxivir Excel Foam CE</b>	Class IIa	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232191507
<b>Oxivir Excel Foam</b>	Class IIa	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232191507
<b>Oxivir Excel Wipe CE</b>	Class IIa	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232191507
<b>Oxivir Excel Wipe</b>	Class IIa	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232191507
<b>Oxivir Sporicide CE</b>	Class IIa	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232191507
<b>Oxivir Sporicide</b>	Class IIa	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232191507
<b>Oxivir Sporicide Wipe CE</b>	Class IIa	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232191507
<b>Oxivir Sporicide Wipe</b>	Class IIa	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232191507
<b>Oxivir CE Plus</b>	Class IIa	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232191507
<b>Oxivir Plus</b>	Class IIa	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232191507
<b>Oxivir Plus J-flex</b>	Class IIa	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232191507

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
Oxivir CE Plus Spray	Class IIa	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232191507
Oxivir Plus Spray	Class IIa	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232191507

**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
2024/04/15	Rev. 00	Initial issue, based on P111F007(e)_Product overview_Rev4.26-24_Diversey