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

P.G.F. Industry Solutions GmbH
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Reference	Contact	Direct Dial	Date
No.: 44 232 160605	E-Mail: medical@tuev-nord.de	Tel.: +49 201 825 2236	15 March 2024

Notified Body Confirmation Letter

Reference: EC-Certificate acc. 93/42/EEC Annex II without (4), No.: 44 232 160605, 35247195

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:

P.G.F. Industry Solutions GmbH
Katzmoosstraße 26a
5161 Elixhausen
Austria
SRN: AT-MF-000000310

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

TÜV NORD CERT GmbH TÜVNORD Am TÜV 1, 45307 Essen

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

i. A. Dr. Benjamin Hoy
TIC Manager MDR
Medical Devices International
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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
Granudacyn® Wundspüllösung Extern: 360150 Intern: 350500	Class III	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Granudacyn® Wundspüllösung Extern: 360110 Intern: 350550	Class III	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Granudacyn® Wundspüllösung Extern: 360100 Intern: 350400	Class III	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Granudacyn® Wundspüllösung Extern: 360111 Intern: 350450	Class III	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Granudacyn® Wundspüllösung Extern: 360101 Intern: 350050	Class III	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Granudacyn® Wundspüllösung Extern: 360103 Intern: 350200	Class III	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Granudacyn® Wundspüllösung Extern: 360104 Intern: 350300	Class III	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Granudacyn® Wundspüllösung Extern: 360102 Intern: 350100	Class III	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Granudacyn® Wundgel Extern: 360107 Intern: 351050	Class III	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Granudacyn® Wundgel Extern: 360108 Intern: 351150	Class III	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Granudacyn® Wundgel Extern: 360112 Intern: 351100	Class III	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Granudacyn® Wundgel Extern: 360113 Intern: 351200	Class III	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Granudacyn® Wundgel Extern: 360106 Intern: 351250	Class III	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605

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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
Veriforte ™ med Wundspüllösung 300500	N/A	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Veriforte ™ med Wundspüllösung 300000	N/A	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Veriforte ™ med Wundspüllösung 300400	N/A	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Veriforte ™ med Wundspüllösung 300050	N/A	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Veriforte ™ med Wundspüllösung 300100	N/A	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Veriforte ™ med Wundspüllösung 300200	N/A	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Veriforte ™ med Wundspüllösung 300300	N/A	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Veriforte ™ med Wundspüllösung 300001	N/A	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Veriforte ™ med Wundspüllösung 300401	N/A	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Veriforte ™ med Wundspüllösung 300051	N/A	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Veriforte ™ med Wundgel 301400	N/A	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Veriforte ™ med Wundgel 301050	N/A	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Veriforte ™ med Wundgel 301300	N/A	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605

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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
Veriforte ™ med Wundgel 301100	N/A	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Veriforte ™ med Wundgel 301150	N/A	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Veriforte ™ med Wundgel 301200	N/A	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Veriforte ™ med Wundgel 301250	N/A	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Veriforte ™ med Wundgel 301051	N/A	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Veriforte ™ med Wundgel 301101	N/A	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Veriforte ™ med Mundspüllösung 302000	N/A	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Veriforte ™ med Mundspüllösung 302300	N/A	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Veriforte ™ med Mundspüllösung 302100	N/A	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Veriforte ™ med Mundspüllösung 302200	N/A	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Granudacyn® Mundspüllösung GD101 Intern: PN 352100	N/A	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605
Granudacyn® Mundspüllösung GD102 Intern: PN 352200	N/A	N/A	93/42/EEC Annex II without (4) Certificate No.: 44232160605

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/01/10	Rev 00	Initial issue based on P111F007_Produktliste_2022-09-16