TÜVNORD

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Our / Your 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.: HD 60131322 0001 21197341 017

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:

MediPac GmbH
Eduard-Rhein-Str. 1-3
53639 Königswinter
Deutschland
DE-MF-000016854

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(AIMDD) or Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer signed the written agreement under MDR by the date of MDD/AIMDD certificate expiry; or provided evidence that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

TÜVNORD i. V.
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i. V. Caroline Schmidt
Deputy Head of Project Management

Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

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i. A. Benjamin Hoy
TIC Manager MDR

Medical Devices International
TÜV NORD CERT GmbH
Notified Body for Medical Devices

TÜVNORD

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
N/A	N/A	N/A	N/A

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
Vacuum bottles 250ml 42556256VFLXX	Class IIa	N/A	93/42/EEC Annex II without (4) Certificate No.:HD 60131322 0001; NB0197
Vacuum bottles 500ml 42556256VFLXX	Class IIa	N/A	93/42/EEC Annex II without (4) Certificate No.:HD 60131322 0001; NB0197
Sodium Citrate solution 3,13 % Ampules 10 ml 42556256NATRATN2	Class IIb	N/A	93/42/EEC Annex II without (4) Certificate No.:HD 60131322 0001; NB0197
Sodium Citrate solution 3,13 % Injection bottles 100 ml 42556256NATRATN2	Class IIb	N/A	93/42/EEC Annex II without (4) Certificate No.:HD 60131322 0001; NB0197
Transfusion sets 42556256TFSY3	Class IIa	N/A	93/42/EEC Annex II without (4) Certificate No.:HD 60131322 0001; NB0197

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/06/17	Rev 00	Initial issue based on 20240306 P111-F-007
YYYY/MM/DD	XXXXXXXXX	Addition of device XYZ to the list
YYYY/MM/DD	XXXXXXXXX	Removal of device XYZ to the list