



Pacific Hospital Supply Co., Ltd.
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Date:	Our reference:	Your reference:
2024-02-19	PRJC-66849-2008-PRC-TWN	9920-2017-CE-RGC-NA-PS Rev.3.0 9922-2017-CE-RGC-NA-PS Rev.2.0

Confirmation Letter

This letter confirms that, DNV Product Assurance AS, a Notified Body (NB) designated against Regulation (EU) 2017/745 (MDR) and identified by the number NB 2460 on NANDO, has received a formal application in accordance with Section 4.3, first subparagraph of Annex VII of MDR from

Pacific Hospital Supply Co., Ltd.

Manufacturer has formally requested DNV for MDD extension and sign a written Certification Agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR

Status:

We, DNV Product Assurance AS, hereby confirm that Certification Agreement is in process. The following activities are included in certification agreement to be covered of the existing MDD_93/42/EEC as amended certificate number _ 9920-2017-CE-RGC-NA-PS Rev.3.0/ 9922-2017-CE-RGC-NA-PS Rev. 2.0

The transition timelines that apply to the devices covered by the certification agreement, 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 as the transition timelines that apply to the devices covered by the agreement 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 as

- 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)

Lin,
Dennis
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by Lin, Dennis
Date:
2024.02.19
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Dennis Lin

DNV Business Assurance Co., Ltd, Product Assurance Director

