Notified Body Confirmation Letter Reference: C607227

To whom it may concern,

Confirmation of receipt of a formal application and conclusion of written agreement in the framework of Regulation EU 2023/607 amending Regulations (EU) 2017/745 as regards the transitional provisions for certain medical devices.

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 and has signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII of MDR with the following manufacturer:

La-med Healthcare Pvt. Ltd.

Plot no: 136 Sector 24 Faridabad Haryana 121005 India

The devices covered by the formal application and the written agreement mentioned above are listed in Table 1 below.

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issued under Directive 93/42/EEC (MDD) that expired after 26 May 2021 and before 20 March 2023, without having been withdrawn, this letter also confirms that the manufacturer submitted the MDR application and signed the written agreement by the date of MDD certificate expiry; or provided evidence that a competent authority of a Member State had granted a derogation/exemption from the applicable conformity assessment procedure in accordance with Article 59(1) of MDR or Article 97(1) of the MDR 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 120.3 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)

Place and date:
Høvik, 2023.04.25

For the issuing office:
DNV Product Assurance AS – Notified Body 2460
Veritasveien 1, 1363 Høvik, Norway

Menaka Singh
Management Representative

Table 1: Devices covered by this letter:

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review 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
Device 1: IV CANNULA, **Basic UDI-DI:** 8903172PIVCHJ	Rule 7, Surgically Invasive Class IIa, Placed on the market in sterile condition	N/A	Certificate Number: 11701-2017-CE-IND-NA-PS, Rev. No. 1.0; NB number: 2460; Expiry date: 6th Jan 2023.
Device 2: IV Cannula with Safety Features, **Basic UDI-DI:** 8903172SIVC8U	Rule 7, Surgically Invasive Class IIa, Placed on the market in sterile condition	N/A	Certificate Number: 11701-2017-CE-IND-NA-PS, Rev. No. 1.0; NB number: 2460; Expiry date: 6th Jan 2023.
Device 3: Infusion Set, **Basic UDI-DI:** 8903172INFS6X	Rule 7, Surgically Invasive Class IIa, Placed on the market in sterile condition	N/A	Certificate Number: 11701-2017-CE-IND-NA-PS, Rev. No. 1.0; NB number: 2460; Expiry date: 6th Jan 2023.
Device 4: Measured Volume Burette Set **Basic UDI-DI:** 8903172MVBS8P	Rule 7, Class IIa, Placed on the market in sterile condition	N/A	Certificate Number: 11701-2017-CE-IND-NA-PS, Rev. No. 1.0; NB number: 2460; Expiry date: 6th Jan 2023.
Device 5: Three Way Stop Cock **Basic UDI-DI:** 8903172TWSCAY	Rule 2, Class IIa Non-Invasive, Placed on the market in sterile condition	N/A	Certificate Number: 11701-2017-CE-IND-NA-PS, Rev. No. 1.0; NB number: 2460; Expiry date: 6th Jan 2023.

Device name / Basic UDI-DI (under MDR application)	MDR Device classification (as proposed by the manufacturer and verified at the quotation request review 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
Device 6: Extension Tubing **Basic UDI-DI:** 8903172EXTT8Z	Rule 2, Class IIa Non-Invasive, Placed on the market in sterile condition	N/A	Certificate Number: 11701-2017-CE-IND-NA-PS, Rev. No. 1.0; NB number: 2460; Expiry date: 6th Jan 2023.
Device 7: Blood Transfusion Set **Basic UDI-DI:** 8903172BTFS6C	Rule 7, Class IIa, Placed on the market in sterile condition	N/A	Certificate Number: 11701-2017-CE-IND-NA-PS, Rev. No. 1.0; NB number: 2460; Expiry date: 6th Jan 2023.
Device 8: Close Wound Suction Unit **Basic UDI-DI:** 8903172CWCU6V	Rule 7, Surgically invasive, Class IIa Placed on the market in sterile condition	N/A	Certificate Number: 11701-2017-CE-IND-NA-PS, Rev. No. 1.0; NB number: 2460; Expiry date: 6th Jan 2023.
Device 9: Ryle's Tube **Basic UDI-DI:** 8903172RYTBAV	Rule 5, Invasive with respect to body orifice, Class IIa, Placed on the market in sterile condition	N/A	Certificate Number: 11701-2017-CE-IND-NA-PS, Rev. No. 1.0; NB number: 2460; Expiry date: 6th Jan 2023.

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2023/04/25	C607227	Initial issue

Lack of fulfilment of conditions

The following may render this letter of confirmation invalid:

- Lack of compliance to the requirements of Regulation (EU) 2023/607
- Significant changes to design or intended purpose of the devices
- Changes in the quality system affecting production
- Periodical audits not held within the timeframe

MDR AGREEMENT CONFIRMATION LETTER

Certificate Number	**NB confirmation letter ref. no-C607227**
Status	**Issued/Current**
Scheme	Medical Device Regulation (EU) 2017/745
Account Name	La-med Healthcare Pvt. Ltd.
Valid Until	December 31, 2028
Scope	Design, Production and final inspection / testing of Sterile Disposable Devices.
Accreditation Body	NoMA

SITES: (0)

1. (primary site)

Scope: