Manufacturer's Self-Declaration

in relation to Regulation 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, in particular with respect to:

- the validity of certificates issued under Council Directive 93/42/EEC on Medical Devices (MDD) (Directive Certificates) *and/or*[1]
- the compliance of the devices and us as their manufacturer with the conditions for the continued placing on the market and putting into service

Manufacturer name	Foremount Enterprise Co., Ltd.
Manufacturer address and contact details	No. 17, Alley 15, Lane 5, Shenan Street., Shengang Dist., Taichung City, 42944 Taiwan
Single Registration Number (SRN) (if available)	TW-MF-000006734

Authorised Representative name (if applicable)	Advena Ltd.
Authorised Representative address and contact details	Tower Business Centre, 2nd Flr, Tower Street, Swatar, BKR 4013 Malta
Single Registration Number (SRN) (if available)	MT-AR-000000234

Notified body name (if applicable)	DNV Product Assurance AS □ See attached schedule
Notified body number (if applicable)	2460 □ See attached schedule
Directive Certificate number(s) to which this confirmation is made (if applicable)	10485-2017-CE-RGC-NA-PS Rev. 2.0 □ See attached schedule
Original expiry date as indicated on the Directive	26 May 2024

[1] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body.

Certificate prior to the extension of the validity (if applicable)	□ See attached schedule
End date of extended validity/transition period	December 31 2028 □ See attached schedule

We, as the manufacturer declare under our sole responsibility:

- for the above listed **Directive Certificate** (or see attached schedule, if multiple certificates) the conditions for the legal extension of validity as required in Article 120.2 of the MDR are met *and/or*[2]
- the listed **device(s)** in the attached schedule and we as their manufacturer are in compliance with the conditions listed in Article 120.3c of the MDR for continued placing on the market and putting into service,

namely by fulfilling the following conditions:

➢ **Directive Certificate(s)** as listed above or in the attached schedule

- Directive Certificate(s) covering the listed device(s) was/were issued after 25 May 2017, was/were valid on 26 May 2021, was/were not withdrawn by 20 March 2023
- *Choose applicable statements:*

☐ Expired *before* 20 March 2023:

☐ Before the original date of expiry as indicated on the Directive Certificate, we and the notified body have signed a written agreement in accordance with Section 4.3, second subparagraph of Annex VII to this Regulation for the conformity assessment in respect of the device covered by the expired certificate or in respect of a device intended to substitute that device

☐ A Competent Authority has granted a derogation from the applicable conformity assessment procedure in accordance with Article 59(1) MDR (may be provided upon request)

☐ A Competent Authority has required the manufacturer, in accordance with Article 97(1) MDR, to carry out the applicable conformity assessment procedure (may be provided upon request)

■ Expired/expires *after* 20 March 2023:

■ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by

[2] The first condition is not applicable in case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body

us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Up-classified devices**

In case of devices for which the conformity assessment procedure pursuant to MDD did not require the involvement of a notified body, for which the declaration of conformity was drawn up prior to 26 May 2021 and for which the conformity assessment procedure pursuant to this Regulation requires the involvement of a notified body:

Choose one applicable statement:

☐ A formal application to the notified body in accordance with Section 4.3, first subparagraph of Annex VII MDR for conformity assessment has been made or will be made/submitted by us to a notified body no later than 26 May 2024 for the device(s) listed in the attached schedule or its substitute and a signed written agreement is/will be in place in accordance with Section 4.3, second subparagraph of Annex VII MDR before 26 September 2024.

☐ We do not intent to lodge an application for conformity assessment by 26 May 2024, therefore the transition period will end on 26 May 2024.

➢ **Quality Management System (QMS)**

- *Choose one applicable statement:*

■ A QMS in accordance with Article 10(9) MDR will be put in place by no later than 26 May 2024.

☐ A QMS in accordance with Article 10(9) MDR is in place.

☐ A notified body has issued the attached certificate for the MDR-compliant QMS.

➢ **Device(s) as listed in the attached schedule**

- The device(s) continue to comply with the AIMDD or MDD.
- The device(s) has/have not been significantly changed in its/their design and intended purpose since 26 May 2021.
- The device(s) do not present an unacceptable risk to health or safety of patients, users or other persons, or to other aspects of the protection of public health.

Signed for and on behalf of the manufacturer:

Full Company Name: Foremount Enterprise Co., Ltd.

Location & Date: Taichung City, Taiwan & 2024/04/03

Signature, Print Name, Title



Joanne Shih

Management Representative

Schedule of Devices

The above Manufacturer's Declaration is valid for the following devices:

Identification of the device Device name / Basic UDI-DI (under MDR application)	**MDR Device classification**	**If the MDR device is a substitute device, identification of the corresponding MDD device**	**MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification (Name and number)**	**Original expiry date as indicated on the Directive Certificate prior to the extension of the validity** (if applicable)	**End date of extended validity/transition period**
Ventilation Mask / 471987189FM2AD01004N	IIa	Disposable Aircushion Mask	10485-2017-CE-RGC-NA-PS Rev. 2.0 2460	**2024.5.26**	**2028.12.31**
Respiratory circuit and Kits / 471987189FM2AD03004Y	IIa	Breathing Circuit	10485-2017-CE-RGC-NA-PS Rev. 2.0 2460	**2024.5.26**	**2028.12.31**
Respiratory circuit Accessories (Reservoir bag) / 471987189FM2AD03004Y	IIa	Breathing Circuit Accessories (Reservoir bag)	10485-2017-CE-RGC-NA-PS Rev. 2.0 2460	**2024.5.26**	**2028.12.31**
Respiratory circuit Accessories (Water trap) / 471987189FM2AD03004Y	IIa	Water trap	10485-2017-CE-RGC-NA-PS Rev. 2.0 2460	**2024.5.26**	**2028.12.31**
Intubation Device / 471987189FM2AS0400AA	IIa	Bougie / Introducer	10485-2017-CE-RGC-NA-PS Rev. 2.0 2460	**2024.5.26**	**2028.12.31**
CPR Mask / 471987189FM2AD05005A	IIa	Pocket Size Resuscitator	10485-2017-CE-RGC-NA-PS Rev. 2.0 2460	**2024.5.26**	**2028.12.31**

Notified Body Confirmation Letter Reference: C684436

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, 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:

Foremount Enterprise Co., Ltd.
No. 17, Alley 15, Lane 5,
Shenan Street.,
Shengang Dist.,
42944 Taichung City
Taiwan

SRN Number: TW-MF-000006734

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 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 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.

Place and date:
Høvik, 27.05.2024

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

Menaka Singh
Management Representative

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)

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 and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Ventilation Mask / 471987189FM2AD01004N	Class IIa	**Disposable AirCushion Mask** - Classic Cushion Mask I - Classic Cushion Mask II - Rotation Mask (Name Change Only)	10485-2017-CE-RGC-NA-PS Rev. 2.0 NB Number: 2460
Respiratory circuit and Kits / 471987189FM2AD03004Y	Class IIa	**Respiratory Care Devices / Breathing Circuit** (Name Change Only)	10485-2017-CE-RGC-NA-PS Rev. 2.0 NB Number: 2460
Respiratory circuit Accessories (Reservoir bag) / 471987189FM2AD03004Y	Class IIa	**Respiratory Care Devices / Breathing Circuit** (Name Change Only)	10485-2017-CE-RGC-NA-PS Rev. 2.0 NB Number: 2460
Respiratory circuit Accessories (Water trap) / 471987189FM2AD03004Y	Class IIa	**Respiratory Care Devices / Water trap** (Name Change Only)	10485-2017-CE-RGC-NA-PS Rev. 2.0 NB Number: 2460
Intubation Device / 471987189FM2AS0400AA	Class IIa	**Respiratory Care Devices / Bougie / Introducer** (Name Change Only)	10485-2017-CE-RGC-NA-PS Rev. 2.0 NB Number: 2460
CPR Mask / 471987189FM2AD05005A	Class IIa	**Respiratory Care Devices / Pocket Size Resuscitator** (Name Change Only)	10485-2017-CE-RGC-NA-PS Rev. 2.0 NB Number: 2460

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 and 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 device	MDD Certificate Reference(s) of the devices under MDR application, and the NB Identification
Not Applicable			

Confirmation Letter Revision History

Date	NB internal reference traceable to each version of the letter	Action
2024/05/27	C684436	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.

DNV·GL

EC CERTIFICATE

Full Quality Assurance System

Certificate No.:	Project No.:	Valid Until:
10485-2017-CE-RGC-NA-PS Rev. 2.0	PRJC-15495-2007-PRC-RGC	27 May 2024

This is to certify that the quality system of:

Foremount Enterprise Co., Ltd.

No. 17, Alley 15, Lane 5, Shenan St., Shengang Dist., Taichung City 42944, Taiwan

For design, production and final product inspection/testing of:
RESPIRATORY CARE DEVICES

Has been assessed with respect to:
THE CONFORMITY ASSESSMENT PROCEDURE DESCRIBED IN ANNEX II EXCLUDING SECTION 4 OF COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES, AS AMENDED

and found to comply.

Further details of the product(s) and conditions for certification are given overleaf.

Place and date:
Høvik, 23 November 2020

For:
DNV GL PRESAFE AS

Notified Body No.: 2460

Tone Kolpus

Tone Elise Kolpus

The certificate is digitally verified by blockchain technology. For more info, see www.dnvgl.com/assurance/certificates-in-the-blockchain.html

Notice: The Certificate is subject to terms and conditions as set out in the Certification Agreement. Failure to comply may render this Certificate invalid.
NOTIFIED BODY: DNV GL PRESAFE AS, Veritasveien 3, N-1363 Høvik, Norway - Registered Enterprise No: NO 997 067 401 MVA .

Certificate No.:
10485-2017-CE-RGC-NA-PS Rev. 2.0

Project No.:
PRJC-15495-2007-PRC-RGC

Valid Until:
27 May 2024

Jurisdiction

Application of Council Directive 93/42/EEC of 14 June 1993, adopted as "Forskrift om Medisinsk Utstyr" by the Norwegian Ministry of Health and Care Services.

Certificate history:

Revision	Description	Issue Date
0.0	Replaces the certificate 86460-2010-CE-RGC-NA Rev. 3.0 (NB 0434) following the transfer of Notified Body functions to DNV GL NEMKO Presafe AS (NB 2460).	25-08-2017
1.0	Change EU Representative	04-12-2019
2.0	Recertification	23 November 2020

Products covered by this Certificate:

Product Description	Product Name	Class
Respiratory Care Devices	Disposable AirCushion Mask - Classic Cushion Mask I - Classic Cushion Mask II - Rotation Mask Silicone Mask Airway - Berman Airway - Rigid Guedel Airway - Soft Guedel Airway Nasal Airway Bougie / Introducer Oxygen Mask Aerosol Mask High Concentration Oxygen Mask Disposable CPAP Mask Nasal Cannula Breathing Circuit Water trap Pocket Size Resuscitator Manual Resuscitator CPR Face Shield	IIa

The complete list of devices is filed with the Notified Body

Certificate No.:
10485-2017-CE-RGC-NA-PS Rev. 2.0

Project No.:
PRJC-15495-2007-PRC-RGC

Valid Until:
27 May 2024

Sites covered by this certificate

Site Name	Address
Foremount Enterprise Co., Ltd. - Head office	No. 17, Alley 15, Lane 5, Shenan St., Shengang Dist., Taichung City 42944, Taiwan
Foremount Enterprise Co., Ltd. - Factory	No. 257, Sec. 5, Changping Rd., Shengang Dist., Taichung City 42944, Taiwan

EU Representative

Name	Address
Obelis s.a.	Boulevard Général Wahis 53, 1030 Brussels Belgium

Terms and conditions

The certificate is subject to the following terms and conditions:

- Any producer (see 2001/95/EC for a precise definition) is liable for damage caused by a defect in his product(s), in accordance with directive 85/374/EEC, as amended, concerning liability of defective products.
- The certificate is only valid for the products and/or manufacturing premises listed above.
- The Manufacturer shall fulfil the obligations arising out of the quality system as approved and uphold it so that it remains adequate and efficient.
- The Manufacturer shall inform Presafe of any intended updating of the quality system and Presafe will assess the changes and decide if the certificate remains valid.
- Periodical audits will be held, in order to verify that the Manufacturer maintains and applies the quality system. Presafe reserves the right, on a spot basis or based on suspicion, to pay unannounced visits.

The following may render this Certificate invalid:

- Changes in the quality system affecting production.
- Periodical audits not held within the allowed time window.

Conformity declaration and marking of product

When meeting with the terms and conditions above, the producer may draw up an EC declaration of conformity and legally affix the CE mark followed by the Notified Body identification number of Presafe.

End of Certificate

APPENDIX TO EC CERTIFICATE

Appendix to Certificate no.:
10485-2017-CE-RGC-NA-PS Rev.2.0

Valid Until:
27 May 2024

This is an Appendix issued to EC Certificate issued for manufacturer:
Foremount Enterprise Co., Ltd.

originally issued in compliance with:
the Council Directive 93/42/EEC on Medical Devices, as amended

Based on assessment performed, the following changes to the certification has been accepted as compliance with Council Directive 93/42/EEC on Medical Devices has been established.

A device already covered by the certification is placed on the market under an additional name or Identifier.

Appendix History		
Revision	**Description**	**Issued Date**
0.0	EU Representative Change	17 January 2023
1.0	A device already covered by the certification is placed on the market under an additional name or Identifier. Add brand name for Classic Cushion Mask II: Air cushion masks, valve, AIR CUSHION MASK, Air Cushion Mask Rotation Mask: Rotation Mask, valve, I Air Cushion Face Mask	22 June 2023

Place and date:
Høvik, 22 June 2023

For the issuing office:
DNV Product Assurance AS - Notified Body 2460