

United States of America  
State of Ohio  
Office of the Secretary of State

*I, **FRANK LAROSE**, Secretary of State, do hereby certify that I am the duly elected, qualified and acting Secretary of State of the State of Ohio, and I further certify that*

**ELIZABETH A. PROCTOR**

*a Notary Public who signed the attached document was commissioned as a Notary Public commencing on NOVEMBER 31, 2022. The commission expires on OCTOBER 31, 2027.*

*This certification certifies only the authenticity of the signature of the official who signed the document, the capacity in which that official acted, and where appropriate, the identity of the seal or stamp, which the document bears. This certification does not imply that the contents of the document(s) are correct, nor that they have the approval of this office.*

*IN TESTIMONY WHEREOF, I have hereunto subscribed my name and affixed the official Seal of the Secretary of State of Ohio, at Columbus, Ohio, this 3<sup>rd</sup> day of October, 2024.*



**Frank LaRose**  
Secretary of State



*This certifies that **PN Medical** has implemented a quality system in compliance with*  
**US FDA 21 CFR 820 Quality System Regulations (Regulations for Good Manufacturing Practices - GMP)**

Issuance Date: 01October2024

Expiry Date: 01October2025

*and the organization is currently registered with US FDA in compliance with*  
**US FDA 21 CFR 807 Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices**  
*for the year 2024.*

Susan Carbone  
Manager, Quality and Regulatory

**NOTARY**

*State of Ohio, County of Cuyahoga*  
*The foregoing instrument was acknowledged*  
*before me this 1st day of October, 2024*  
by Elizabeth A. Proctor Notary Public.  
My Commission Expires 10-31-2027.



3505 Lake Lynda Dr, Suite 200  
Orlando, Florida, 32817 USA

United States of America  
State of Ohio  
Office of the Secretary of State

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**Frank LaRose**  
Secretary of State





## CERTIFICATE OF COMPLIANCE



*This certifies that IMATS (Injection Moulding & Tooling Services, S.A.) has implemented a quality system in compliance with*

**US FDA 21 CFR 820 *Quality System Regulations* (Regulations for Good Manufacturing Practices - GMP)**

Issuance Date: 01October2024

Expiry Date: 01October2025

*and the organization is currently registered with US FDA in compliance with*

**US FDA 21 CFR 807 *Establishment Registration and Device Listing for Manufacturers and Initial Importers of Devices***

*for the year 2024.*

A handwritten signature in blue ink, appearing to read "Susan Carbone".

Susan Carbone  
Manager, Quality and Regulatory

### NOTARY

State of Ohio, County of Cuyahoga

The foregoing instrument was acknowledged  
before me this 1st day of October, 2024

by Elizabeth A. Proctor Notary Public.

My Commission Expires 10-31-2027.



3505 Lake Lynda Dr, Suite 200  
Orlando, Florida, 32817 USA



**Certificado de Registro de Empresa**  
**Conforme a las exigencias de la norma**  
**INTE/ISO 9001:2015**  
**Sistemas de gestión de la calidad. Requisitos.**

La Asociación Instituto de Normas Técnicas de Costa Rica, INTECO, ubicada en San José, Costa Rica, certifica que la organización:

National Institute of Standardization Association of Costa Rica, INTECO - San José, Costa Rica, certifies that the organization:



INJECTION MOULDING & TOOLING SERVICES SA

**INJECTION MOULDING AND TOOLING SERVICES S.A.**  
**(IMATS)**

Cumple con los requisitos para el siguiente alcance:

Producción y comercialización de piezas y componentes de alta precisión, mediante el proceso de inyección, mecanizados de segundo proceso y acabados finales como: soldadura ultrasónica, impresión industrial, programación de máquinas CNC y dimensionados de partes industriales.

Comercialización de partes y accesorios para maquinaria a alta precisión, moldes y sus componentes, mantenimiento de moldes y pruebas de moldes.

Complies with the requirements for the following scope:

Production and commercialization of high precision parts and components, through the injection process, second process machining and final finishes such as: ultrasonic welding, industrial printing, programming of CNC machines and dimensioning of industrial parts.

Commercialization of parts and accessories for high precision machinery, molds and their components, mold maintenance and mold testing".

Que opera en las instalaciones ubicadas en:

which is carried out in

Parque Industrial Zeta Edificio # 30 A, Guadalupe, Cartago.

Firmado

digitalmente por

ALVARO TORRES

CHINCHILLA (FIRMA)

Fecha: 2024.06.11

20:56:52 -06'00'

Director de operaciones

Fecha de emisión: 2018/08/09

Fecha de renovación: 2024/05/03

Fecha de expiración: 2027/08/09

El presente certificado es válido exclusivamente para el proceso descrito, no tiene validez sin su correspondiente alcance de la certificación, donde se indica el servicio, las especificaciones y los documentos normativos aplicables, así como número de registro. En caso de duda siempre prevalecerá el alcance en español. Este certificado es propiedad de INTECO y deberá ser devuelto a su solicitud; se prohíbe su reproducción excepto con la aprobación por escrito de parte de INTECO. This certificate is valid only for the process described, is not valid without a corresponding scope of certification, indicating the services, specifications and normative documents, and registration number. In case of doubt the spanish written scope will prevail over the english written scope. This certificate is owned by INTECO and must be returned upon request; Reproduction is prohibited except with the written approval of INTECO. ESMC-40 Versión 2.0 Edición 21A





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**Frank LaRose**  
Secretary of State

Medical Device Control Division  
Thai Food and Drug Administration  
Ministry of Public Health

October 1, 2024

Dear Sir/Madam,

Subject: Letter of Appointment for Sole Agency

**PN Medical, Inc.**, as the Product Owner, hereby authorizes **Al-Essa Med Co. For Trading in Medicines, Medical Equipment, Devices and Supplies WLL** (P.O.Box 3562, Safat 13036 Kuwait Dajeej Area Block 1 Street 79 Building 44 Sultan Bin Essa Complex, KUWAIT) as the appointed local agent and the sole and/or exclusive agent in Kuwait to register and to prepare and submit applications for the evaluation and registration of medical devices to the Kuwait Ministry of Commerce and Ministry of Health on our behalf.

**This authorization shall apply to the following medical devices:**

- The Breather (Pink)
- The Breather (Blue)
- Breather Recover (Green)

We also authorize **Al-Essa Med Co. For Trading in Medicines, Medical Equipment, Devices and Supplies WLL** to make declarations and to submit documents on our behalf, regarding the above medical devices, in support of this application. These declarations and submissions are made pursuant to the requirements of Kuwait's Ministry of Health (MOH) ministerial decree number 13 of 2022 and any other applicable laws that may also be in force.

This authorization shall remain in effect until our notification to the Kuwait Ministry of Commerce and Ministry of Health in writing that the authorization is revoked.

We undertake to provide post-market support and assistance to the Registrant as may be required in relation to any matter involving the above medical devices.

Yours Sincerely,



Susan Carbone, Owner



Notary  
State of Ohio, County of Cuyahoga  
The foregoing instrument was acknowledged before me  
this 1st day of October, 2024  
by Elizabeth A. Proctor  
PN MEDICAL, Inc  
Headquarters - Orlando, FL  
www.pnmedical.com - care@pnmedical.com - 877-414-4449  
Helping people worldwide improve their cardiopulmonary health and performance