THERMO-PLY, INC.

Technical Documentation: Biocompatibility

To whom it may concern,

The following three pages are excerpts from section (11.0 Product Verification and Validation) of the MDR technical file regarding product biocompatibility.

Sincerely,

Ryan Fay

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Vice President

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11.0 Product Verification and Validation

11.1 General

Product verification and validation is accomplished through the ISO 13485 QMS system.

Attachment 6 – ISO 13586 Certificate.pdf

A. Product Design and Development: Implement a rigorous design control process that includes risk management, prototype testing, and validation to create prosthetic liners and sleeves that meet user needs and are safe for use.

B. Supplier Management: Establish criteria for evaluating and selecting suppliers of raw materials, ensuring they meet quality standards. Regularly assess supplier performance and maintain open communication to address any issues promptly.

C. Manufacturing Process Control: Implement strict process controls, including standardized operating procedures, employee training, and equipment maintenance protocols. Regularly monitor and analyze production processes to identify areas for improvement and prevent defects.

D. Quality Control and Testing: Conduct thorough quality inspections and testing at various stages of production to ensure products meet specifications. Implement non-destructive testing methods and inspections to maintain product integrity.

E. Document Control: Maintain a centralized system for document control, ensuring that all documents related to product specifications, procedures, and regulations are current, accessible, and properly version-controlled.

F. Traceability and Recall Procedures: Establish traceability systems to track materials and components used in each product. Develop clear procedures for initiating product recalls if defects or safety issues are identified, ensuring swift and effective response.

G. Customer Feedback and Complaint Handling: Implement a structured process for collecting customer feedback and handling complaints. Analyze feedback to identify trends and areas for improvement. Address customer complaints promptly, investigate root causes, and implement corrective actions.

H. Continuous Improvement: Promote a culture of continuous improvement by conducting regular internal audits, management reviews, and employee training programs. Use data-driven decision-making to identify areas for improvement and implement corrective and preventive actions.

11.1a Engineering tests

N/A: Does not apply to devices.

11.1b Laboratory tests

N/A: Does not apply to devices.

11.1c Simulated use tests

N/A: Does not apply to devices.

11.1d Animal testing

N/A: Does not apply to devices.

11.1e Published literature

N/A: Does not apply to devices.

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11.2 Biocompatibility

11.2a Materials in direct or indirect contact with patient or user

Nr.	Material	Description	Biocompatibility
1	Thermoplastic Gel – polymer blocks	The gel is a TPE, thermoplastic elastomer rubber. The structure is composed of xxx blocks and polymer blocks. The physical structure and association of the blocks, particularly in the presence of heat or processing, offer a high tensile strength and stretch, which make it ideal for prosthetic sleeves.	Pass, commonly known polymers used throughout the industry, know to be a non-irritant.
2	Fabric Cover	The fabric is a textured synthetic high-stretch Nylon consisting of approximately 85% Polyamide and 15% Elastane.	Pass, commonly known polymers used throughout the industry, know to be a non-irritant.

11.2b Tests conducted

In-house patch testing was used to assess the biocompatibility of gels, specifically evaluating their potential to cause skin sensitization or irritation. This test involves applying the gel onto patches, which are then placed on the skin of test subjects to observe reactions.

A. Selection of Test Subjects:
    a. Human Volunteers: Ethical guidelines and informed consent are crucial. Test subjects should be healthy adults with no known skin conditions or allergies.

B. Preparation of Gel Samples:

a. Sample Preparation: Extract the gel to be tested using a suitable solvent, creating a concentration representative of real-world use. Prepare multiple samples if variations in composition or formulation exist.

C. Patch Application:
   a. Patch Preparation: Apply the gel samples onto patches made of hypoallergenic material, such as medical-grade adhesive or non-reactive material.
   b. Patch Application: Affix the gel-loaded patches onto the skin of test subjects. Place the patches on a specific area, usually the upper back, which is marked for proper identification.

D. Patch Duration and Observation:
   a. Duration: Leave the patches on the skin for a specified period, typically 24 or 48 hours, depending on the testing protocol and standards.
   b. Observation: Instruct test subjects not to remove or wet the patches during the testing period. Record any signs of skin redness, swelling, itching, or other adverse reactions.

E. Data Analysis and Reporting:
   a. Data Recording: Record the observed reactions, including their onset, duration, and intensity.
   b. Data Analysis: Compare the results with established guidelines and standards, determining whether the gel causes adverse skin reactions.

F. Quality Control:
   a. Repeat Testing: Conduct repeated patch tests with different batches of the gel, especially if there are changes in the gel's composition, formulation, or source of raw materials.

   b. Internal Review: Have the test results reviewed internally by experts to ensure accuracy and reliability.

11.3 Medicinal Substances

The device does not incorporate or utilize any medical substance as referred in Section 12.1 of Annex I of the Regulation (EU) 2017/745 on medical device.

11.3a/b Substance, identity, source and reason for presence

N/A: Does not apply to devices.

11.3c Safety and performance in the intended application

N/A: Does not apply to devices.