THE ORTHOTIC AND PROSTHETIC ALLIANCE

Executive Summary: O&P Duty-Free Tariff Qualification

For a complete analysis and case law details, see the full memorandum <u>here.</u>¹, and view the O&P qualification flow chart <u>here</u>.

Bottom Line: The Nairobi Protocol (HTSUS 9817.00.96) offers duty-free entry for qualifying O&P devices but requires meeting specific criteria and proper documentation. This represents significant cost savings in import fees for O&P devices, particularly important given O&P providers' challenges absorbing tariff costs due to fixed U.S.-based reimbursement structures.

The Opportunity: Duty-free treatment for articles that are "specially designed or adapted" for individuals with permanent disabilities that substantially limit major life activities.

Key Requirements:

- Specially designed for disability use (not general goods)
- Permanent/chronic impairment (not acute, transient or temporary conditions)
- Complete "articles" and some qualifying accessories and parts

Major Exclusions:

- Certain parts and accessories of braces and artificial limb prosthetics
- Temporary/acute disability items
- Therapeutic and diagnostic articles
- General-use items

Critical Distinction - Article vs. Part: Self-contained, complete items qualify as "articles" (e.g., prosthetic feet, hands, and joints qualify as complete articles). Certain "parts" (e.g., pylons and individual components of prostheses and orthoses typically do not). Complete prosthetic "sets" may qualify entirely if the main device imparts the essential character of the prostheses or orthoses (e.g., Taska Hand that was ruled to be a complete kit qualifying as one article).

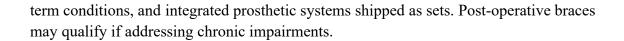
Process: Importers must affirmatively claim duty-free treatment at entry with supporting documentation (ITA-362P form). U.S. Customs and Border Protection (CBP) evaluates eligibility case-by-case based on design, function, and documentation.

Best Candidates: Complete prosthetic devices for limb loss are clearer candidates for duty-free qualification. Strong candidates include custom AFOs, KAFOs, foot drop stimulators for long-

¹ Annika Berlin, 2025 George and Dena Breece Fellow of the National Association for the Advancement of Orthotics and Prosthetics (NAAOP) authored this analysis.

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