

How to Qualify Medical Devices for Duty-Free Import Into the U.S.

Article

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Over the past year, escalating protective tariffs have prompted many domestic and foreign medical device manufacturers to reach out for assistance with duty-free entry of their products into the U.S.

In many cases, relief is available under the little-known international agreement, the Nairobi Protocol, formally known as the Protocol to the Agreement on the Importation of Educational, Scientific and Cultural Materials.

How the Nairobi Protocol Provides Duty-Free Entry

The U.S. implements the Nairobi Protocol through special provision of the Harmonize Tariff Schedule of the United States ("HTSUS") subheadings 9817.00.92, 9817.00.94, and 9817.00.96. To qualify for duty-free treatment under these provisions, two conditions must be met:

1. The product must be specially designed or adapted for the use or benefit of persons with physical or mental disabilities; and
2. The disability must be chronic or permanent, not temporary or short-term.

U.S. Customs and Border Protection (CBP) has issued many rulings identifying products that qualify as being specially designed or adapted for persons with disabilities.

Examples include cochlear implants, insulin pumps, pacemakers, and prosthetic arms as well as masks, headgear, and related components used to treat sleep apnea. By contrast, medical devices intended for general public use, such as wearable devices that measure heart rate, have been found not to qualify for the exemption.

Regarding the second condition, CBP has determined that chronic visual and hearing impairments, diabetes, and mobility and speech disabilities are considered permanent disabilities.

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Should a product qualify for Nairobi Protocol duty-free treatment, that qualification overrides all other tariffs provisions, including those issued under emergency and investigatory powers of the federal government. For example, if a product is subject to IEEPA tariffs but also qualifies for classification under chapter 9817.00.96 duty-free treatment, it will be granted duty-free treatment at entry.

If you currently import products such as medical devices, standard therapeutic or diagnostic equipment, or accessories or components that are not uniquely adapted for disabled users, reach out to us for help.

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