

CLIENT MEMORANDUM

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Betreffend **Tariff exemption for medical devices from Switzerland**

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Is the US tariff wall impenetrable for Swiss medical device manufacturers?

The 39% US tariffs on Swiss medical devices present significant challenges for the industry, particularly for SMEs with limited resources. While production relocation and supply chain adjustments offer only medium-term relief, the Nairobi Protocol provides an immediate legal relief. Learn in our article whether your products qualify for this duty exemption and how to proceed strategically.

On 7 August 2025, the US administration imposed reciprocal **tariffs of 39% on imports from Switzerland** to the United States. These are among the highest worldwide, and far above those applied to EU countries (15%) and the UK (10%). While pharmaceutical products were exempted, medical devices were not.

After the EU, the United States is Switzerland's second most important trading partner for medtech products. Nearly a quarter (23%) of all exports go to the US, corresponding to goods worth CHF 2.8 billion annually.

The new tariff is a **game-changer**. With tariffs of 39%, Swiss manufacturers face an additional annual cost burden of more than CHF 1 billion if no exemptions are applied. It strikes at the heart of Switzerland's export-driven medtech industry. The abrupt introduction, the absence of transition periods, and the selective exemptions for other sectors amplify planning uncertainty and leave manufacturers with little to no time to adapt. Recently built stockpiles will not last long. With profit margins under pressure and supply chains disrupted, there is a risk that US customers will shift to cheaper alternatives, which will have swift and severe ripple effects.

Some companies, such as **Ypsomed Holding**, have already announced plans to relocate part of their production to Germany to benefit from lower EU tariff rates while expanding their US-manufacturing operations. Yet for many manufacturers, reorganising operations through supply chain flexibility, near-shoring, or even establishing a tangible US presence - whether via production, partnerships, or acquisitions - is neither feasible in the short term nor guaranteed to offset the tariff impact. Small and medium-sized enterprises are particularly vulnerable, as they more likely lack the resources to restructure quickly.

Is There a Way Out?

This is not the first time that medical device manufacturers have faced such a challenge in the United States. In 2018–2019, for example, the US imposed punitive tariffs of 25% on medical devices and components imported from China. **ResMed**, a manufacturer of sleep apnoea and respiratory care devices, many of whose components are manufactured in China, argued that its devices and dedicated accessories, such as nasal masks and tubing, were “specially designed for the benefit of persons with a permanent or chronic disability (sleep

apnoea)” and should therefore be exempt from customs duties. Upon ResMed's petition, the competent authority, the U.S. Customs and Border Protection (CBP), held that masks, headgear, and related components for devices to treat sleep apnea qualify for duty free treatment as products for handicapped persons.

Other examples where exemptions were granted include pacemakers, cochlear implants, insulin pumps, and mobility scooters—products clearly distinguishable from consumer goods. By contrast, products that overlap strongly with consumer markets, such as wearable devices for general biometric monitoring, have consistently failed to qualify.

What made this exemption possible?

The international treaty for duty-free trade among signatory countries was initially limited to specified categories of goods, including articles for the blind. The **Nairobi Protocol**, a subsequent amendment in 1976, broadened the scope of this exemption to include goods specifically designed for handicapped persons. In 1982, the United States incorporated the Nairobi Protocol into domestic law, establishing a statutory duty exemption for products specially designed for people with certain health conditions.

Since implementing the Nairobi Protocol domestically, the CBP has issued numerous rulings on whether products qualify as specially designed or adapted for disabled persons. According to published case law, the exemption applies to goods designed for individuals with permanent or chronic physical or mental conditions of a certain severity. These include chronic visual and hearing conditions, as well as diabetes and cardiovascular ailments such as arrhythmia and bradycardia, or mobility and speech disabilities.

In addition to meeting the qualifying criteria, products must also meet **product-specific requirements**: it must be easily distinguishable from similar products designed for use by the general public. Notable examples include blood glucose monitors, artificial heart valves,

text-to-speech devices, and patient-lifting equipment.

By contrast, a wearable device used to measure heart rate and blood flow was found not to qualify as a specially designed product for the handicapped. Although the manufacturer argued that the device was designed to obtain biometric data for people with chronic blood and heart conditions, the CBP ruled that the device "does not have any identifying features that would make it solely usable" for persons with those conditions, and provides biometric data "very similar to other wearables, which are not limited to use for permanent or chronic physical impairments."

Utilising the Nairobi Protocol Duty Exemption: The way forward

The exemption provided by the Nairobi Protocol is not an isolated carve-out from the newly imposed tariffs on foreign medical device manufacturers. Rather, it reflects the United States' long-standing commitment to uphold its international obligations. Experts emphasise that the US administration's stance is no coincidence but a deliberate policy choice, given that it has granted many further tariff exemptions. On this basis, industry observers are confident that foreign medical device manufacturers will continue to benefit from the Nairobi Protocol in the future and thus remain shielded from the impact of the new tariff wall.

Despite its clear benefits, the Nairobi Protocol duty exemption is often overlooked in favour of more complex or costly alternatives. This was understandable when tariffs were low. However, with tariffs now reaching up to 39% and more, importers - particularly for medical devices from Switzerland - should carefully assess whether their products **qualify for an exemption**. To do so, importers should follow the following three steps:

- **Assess eligibility:** Conduct an internal analysis of whether the product is specifically

designed for handicapped persons and distinguishable from general consumer products.

- **Decide on strategy:** Either seek a **binding ruling** from CBP to confirm eligibility under the Nairobi Protocol, or attempt to enter goods under the applicable Nairobi Protocol Harmonized Tariff Schedule subheadings without first obtaining a CBP ruling.
- **Prepare documentation:** Ensure technical and clinical evidence is available to demonstrate design intent and use case, which will be critical in case of CBP review.

Whether a product qualifies under the Nairobi Protocol is open to interpretation. A **binding ruling** provides legal certainty and reduces the risk of costly audits or unexpected duty assessments. However, the ruling process can take several months if not years, which may be too long for companies facing immediate tariff exposure. Without a ruling, importers run the risk that CBP may deny the exemption, leading to retroactive duties and potential penalties. For this reason, we recommend clarifying these issues with an expert on US customs practice.

How should manufacturers proceed?

The Nairobi Protocol exemption offers the most immediate relief for certain medical devices. Manufacturers should act now to: (1) assess whether their products may qualify for a Nairobi Protocol exemption, (2) seek expert advice on US customs law, and (3) prepare robust documentation to support their position. While individual company strategies are crucial, coordinated industry advocacy at the political and trade policy levels will be essential for long-term tariff relief.

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