

# Leveraging the Nairobi Protocol

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## Insights and Compliance with the U.S. Duty-Free Provision for Medical Devices

Online Webinar  
Wednesday, September 3, 2025  
11:00 AM (EST)  
5:00 PM (CEST)

This presentation is for informational purposes only and does not constitute legal advice.



# OVERVIEW


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- I. **Tariff challenges in global trade**
- II. **Nairobi Protocol Duty Exemption**
  - A. What is it?
  - B. Qualifying Conditions
  - C. Eligible vs. Ineligible Products
  - D. CBP's 5-Factor Test
- III. **Relevance for Medical Device Companies**
  - A. Implications for MedTech
- IV. **Call to Action**
  - A. CBP Binding Ruling
  - B. Protest Rights
- V. **Conclusion**

# Tariff Challenges in Global Trade: Current Pressures

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- U.S. tariffs continue to rise causing importers excess strain
  - Strategic planning amid uncertainty
  - Need for efficient mitigation tools

# Nairobi Protocol: What is it?

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- Adopted under UNESCO (1976)
- Duty-free entry for goods for handicapped persons
- U.S. adoption: 1982, codified in 1988
- Implemented in Harmonized Tariff Schedule of the U.S. (HTSUS)



# Nairobi Protocol: Qualifying Conditions

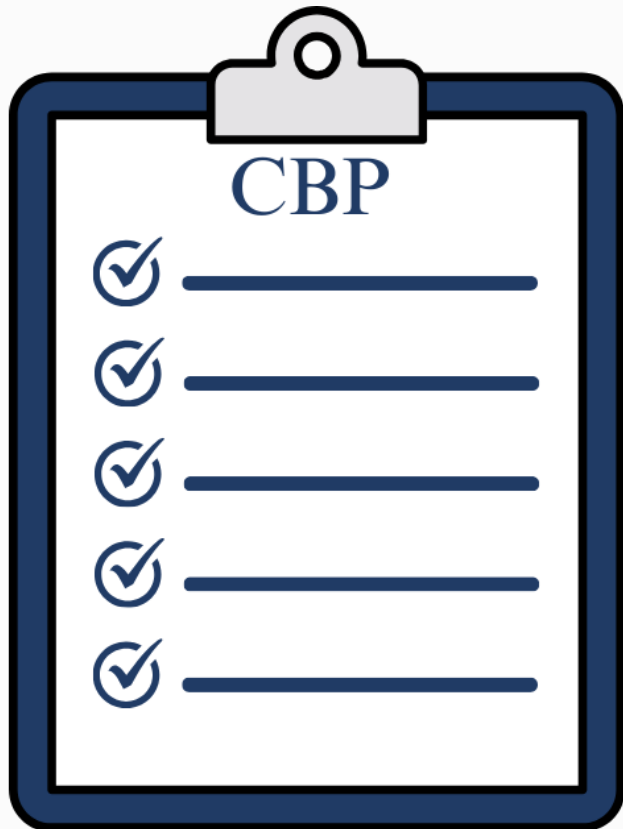
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- "Handicapped persons" = broad scope
- Chronic or permanent conditions
- Substantial limitation
- Examples: diabetes, heart disease, mobility & speech impairments

# Specially Designed: CBP's 5 Factor Test

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1. Physical properties
2. Likelihood of use
3. Importer profile
4. Distribution channel
5. Condition as imported

# Nairobi Protocol: Eligible & Excluded Products

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## Eligible

- Must be specially designed or adapted
- Distinguished from general use items

## Examples:

- Pacemakers
- Blood glucose monitors
- Spinal implants
- Hearing aids

## Excluded

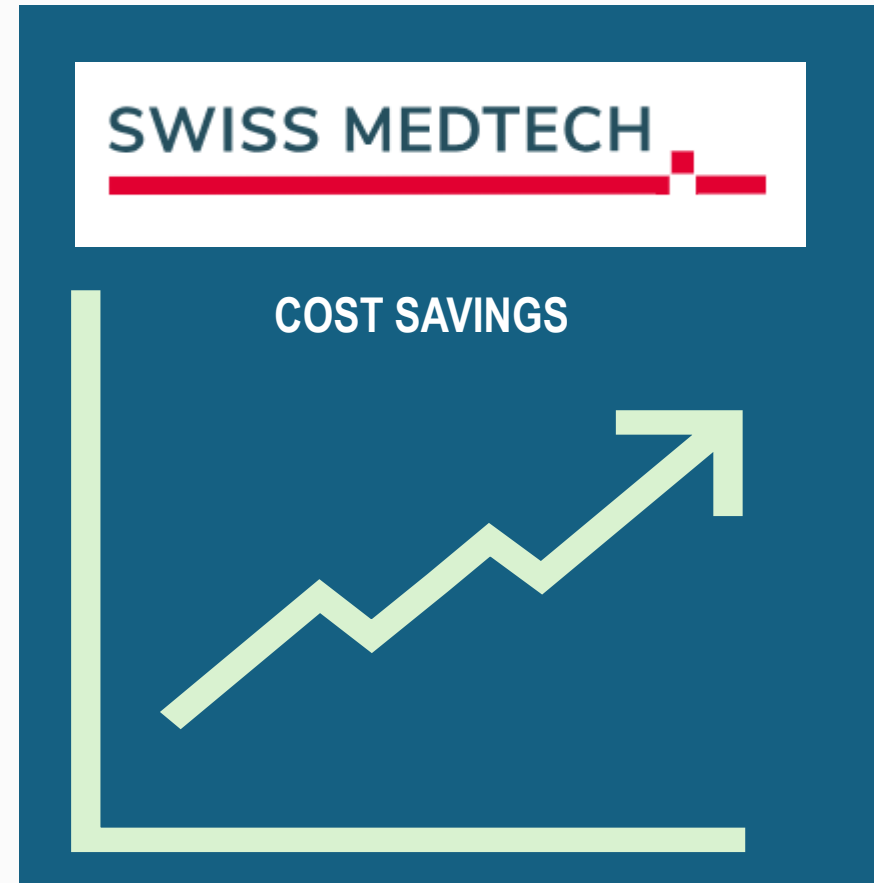
- Therapeutics
- Diagnostics
- Cosmetics
- Medicines & drugs
- Acute or temporary

# Relevance for Medical Device Importers:

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## Implications for MedTech

- Many devices may qualify duty-free
- Duty-free = no reciprocal tariffs
- Significant cost savings available



# Call to Action: Best Practices

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BEST PRACTICE

- Customs declarations = honor system
- “Reasonable Care”
- Assess product eligibility
- Seek expert guidance
- CBP binding ruling for additional certainty

# CBP Binding Ruling: What is it?

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- Importer submits ruling request to CBP
- CBP determines Nairobi Protocol eligibility
- Result = legally binding, official ruling
- Ruling # referenced in import documents
- Provides predictability



# What if Nairobi Duty-Free Treatment is Denied?

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- CBP may question/deny duty-free treatment
- Importer may file a “protest”
- 180-day window after CBP’s decision
- If protest is denied, judicial review is available
- CBP ruling eliminates this uncertainty



# Conclusion

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- Nairobi Protocol = best mitigation tool for Medtech
- Heightened scrutiny, compliance is key
- Obtain expert guidance to review eligibility
- Consider CBP binding ruling for certainty





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**Thank you for your time today!**

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