



**MINISTRY OF FOREIGN AFFAIRS  
OF DENMARK**  
*The Trade Council*

# **NORTH AMERICAN MARKET ACCESS SEMINAR**



**JUNE 20 & 21, 2023**



**EIGTVEDS PAKHUS,  
COPENHAGEN, DENMARK**



## VALUE PROPOSITION

The Danish Trade Council is proud to offer this in-person seminar in Copenhagen to support Danish MedTech SMEs entering the North American market.

Stakeholders and leading industry experts with deep knowledge and experience with the US and Canadian markets will provide valuable content on specific aspects of market access with a particular focus on reimbursement.

The seminar has been developed through discussions with leading industry experts and based on feedback from Danish SMEs.

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## BACKGROUND

Denmark's life science sector offers innovative solutions to global health-care challenges, and North America is a crucial trading partner for Danish companies in this industry. The US is the largest market, with \$7.45 billion in Danish life science exports in 2020.

However, Danish SMEs face significant obstacles to entering these markets due to complex regulatory requirements, reimbursement processes, distribution channels, and entity establishment requirements.

Without adequate knowledge and resources, companies may miss out on potential earnings.

# PROGRAM – DAY 1

**TUESDAY** JUNE 20

**8:30 – 9:00**

**ARRIVAL & BREAKFAST**

**9:00 – 10:30**

**SESSION #1**

Welcome to North America!

Session Opening, Welcome Remarks, and Introduction to The Trade Council

Introduction to US & Canadian Markets

Danish Medical Device Companies That Have Successfully Entered the North American Market: Case Studies

**10:30 – 10:45**

**COFFEE BREAK**

**10:45– 13:10**

**SESSION #2**

Unravelling the Complex US Reimbursement Pathway

Classification of Medical Devices in North America

Introduction to Reimbursement Processes for Medical Devices in the US Market

Reimbursement Coding Systems (CPT, ICD-10-PCS & HCPCS) for Medical Devices in the US Market

**13:10 – 13:40**

**LUNCH**

**13:40 – 14:40**

**SESSION #3**

So You're Coming to Canada, Eh?

Reimbursement Processes for Medical Devices in the Canadian Market

**14:40 – 15:00**

**COFFEE BREAK**

**15:00 – 17:00**

**SESSION #4**

The Regulation of Medical Devices in North America

Developing a Regulatory Strategy for the US Market

Developing a Regulatory Strategy for the Canadian Market

**17:00 – 19:00**

**NETWORKING EVENT**



# PROGRAM – DAY 2

**WEDNESDAY** JUNE 21

**8:30 - 9:00**

**ARRIVAL & BREAKFAST**

**9:00 – 10:45**

**SESSION #5**

Regulation of Emerging Medical Device Technologies and Implementing an Effective Clinical Strategy

Regulatory Considerations Around AI/ML-Based Software as a Medical Device in i) US and ii) Canada

Developing an Effective Clinical Strategy to Facilitate Approval and Reimbursement for Medical Devices in the North American Market

**10:45 – 11:00**

**COFFEE BREAK**

**11:00 – 12:45**

**MEETING SESSION #1**

1:1 Meetings

During these sessions, participating companies will have the opportunity to have a one-on-one meeting with North American market access experts.

**12:45 – 13:15**

**LUNCH**

**13:15 – 15:00**

**MEETING SESSION #2**

1:1 Meetings

During these sessions, participating companies will have the opportunity to have a one-on-one meeting with North American market access experts.





# DON'T MISS OUT ON THIS EXCLUSIVE OPPORTUNITY FOR YOUR SME ORGANIZATION TO GAIN VALUABLE INSIGHTS AND NETWORK WITH LIKE-MINDED PROFESSIONALS!

## PARTICIPATION FEE & DETAILS

For only **DKK 2200** (+ outlays for food/beverages) per organization\* you can send up to two attendees to this exciting event.

*If you are interested in participating please sign-up through the following [link](#).*

## SUPPORTED BY OUR PARTNER ORGANIZATIONS



NAMSA®



*\*Requires that you meet the criteria for an SME; Less than 250 employees; annual turnover not exceeding DKK 375 million and/or an annual balance sheet total not exceeding DKK 320 million in the last financial year; If owned by a parent company/companies by more than 49% and/or has a subsidiary/subsidiaries with an ownership interest of more than 49%, the number of employees and revenue for the whole group must be included.*

# PROJECT TEAM



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