

# MedTech Consultants

Find your consultant among  
members of MedTech Denmark

**MEDICO**  
INDUSTRIEN  
MEDTECH DENMARK

**Medicoindustrien**

Bøge Alle 5

2970 Hørsholm

[www.medicoindustrien.dk](http://www.medicoindustrien.dk)

# MedTech Denmark's consultant brochure

## Are you looking for a consultant in the MedTech industry?

In this brochure, you will find MedTech Denmark's consultant members, who offer a wide range of services that span everything from product development and production to market access, including quality management, regulatory affairs (MDR/IVDR), and other industry-specific legislation.

If you have any questions about the content of the brochure, how to become part of it, or anything else, feel free to send an email to: [medico@medicoindustrien.dk](mailto:medico@medicoindustrien.dk)

## Do you want to be part of MedTech Denmark's consultant brochure?

As part of the membership of MedTech Denmark, you as a consultancy are offered to be part of this brochure.

As a consultant member of MedTech Denmark, you also get exposure to our members and the opportunity to teach at the educations, courses, and seminars in MedTech Denmark's course company MedTech Academy. In addition, consultant members have the opportunity to participate in the many expert groups of MedTech Denmark, on an equal footing with the association's other members, as well as give professional presentations under its auspices.



**The Alexandra Institute** is Denmark's only government-approved Research and Technology Organizations specialized in IT. We advise Danish life sciences organizations on new digital technologies and develop customized solutions based on the latest research and close user involvement.

#### ARTIFICIAL INTELLIGENCE

- Visual AI, such as analysis of (bio-)medical imaging data in 2D and 3D
- Data analysis, e.g., anomaly detection for forecasting and prevention
- Language AI, e.g., RAG solutions in Danish and specialized language

#### DATA ETHICS AND CYBERSECURITY

- Cybersecurity consulting, e.g., NIS2, RED, CRA, AI Act, and more
- Support for secure software development, including security by design, testing, and verification
- Co-founder of the Danish Network for Citizen-Generated Data

#### DIGITAL HEALTH EXPERTISE

- National health IT infrastructure, international standards, and interoperability
- Telemedicine and handling citizen-generated data, such as ePRO and vital metrics
- User insights and involvement in design, development, and implementation

#### Alexandra Institutet

Åbogade 34, Aarhus N &  
Rued Langgaards Vej 7, Kbh S  
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alexandra@alexandra.dk  
www.alexandra.dk



**Andreasen & Elmgaard A/S** provides assistance in all aspects of project management, technical and regulatory consulting, as well as product and production development for the Medical Device, Pharma, and Biotech industries. We are experts in the development of medical devices as well as the development and validation of production processes and equipment.

#### ENGINEERING CONSULTING

- Conceptual Design & Development
- Project Management, Practical Execution, Installation, and Testing
- IT/Automation and 3D CAD Design & Construction

#### PRODUCT, PROCESS & PRODUCTION

- Risk Management, Change, and Deviation Handling
- Development, Qualification, Verification, and Validation
- Optimization and Support of Production, Logistics, and Inventory Management

#### COMPLIANCE

- Documentation and Design Control
- Regulatory Compliance covering both EU and US for the Medical Device, Pharma, and Biotech industries
- Quality Assurance, Quality Systems, and Audits; certified in both ISO9001 and ISO14001

#### Andreasen & Elmgaard A/S

Generatorvej 8C, 2. th  
2860 Søborg  
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info@aoge.dk  
www.aoge.dk





## BIOFARMA LOGISTIK

Logistik | Distribution | Service

**Biofarma Logistik A/S** specializes in tailored logistics solutions for the pharmaceutical industry, prioritizing quality and compliance. We work closely with clients to ensure a seamless, reliable supply chain that adheres to all regulations.

### LOGISTICS SOLUTIONS FOR THE HEALTHCARE SECTOR

- We deliver tailored solutions that meet the requirements for pharmaceuticals and medical devices, focusing on safety and efficiency

### COMPLIANCE WITH MDR AND GDP REGULATIONS

- Our expertise ensures full adherence to both MDR and GDP standards, providing security across the entire supply chain

### EFFICIENT INVENTORY MANAGEMENT

- With a focus on traceability and precision, we offer inventory management that supports effective product handling and minimizes waste

### Biofarma Logistik A/S

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2600 Glostrup

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ordre@biofarma.dk

www.biofarma.dk



## BORGENSGAARD Consulting

**Borgensgaard Consulting** specializes in medical equipment/in vitro diagnostic devices and offers consulting, project management, and specialized services to suppliers, manufacturers, importers, and distributors. Clients range from startups to large organisations.

### QUALITY MANAGEMENT AND COMPLIANCE

- MDR, IVDR, ISO 13485, 21 CFR Part 820 and MDSAP
- QMS and electronic document control systems
- Deviations, CAPA and systematic problem solving

### PRODUCTION

- Requirements to clean room production (ISO 14644), risk for contamination
- Process risk analysis and validation (DQ, IQ, OQ, PQ)
- Software validation, GAMP 5, 21 CFR part 11

### DESIGN CONTROL

- Design and development plans, requirements specifications, risk management (ISO 14971) and labeling
- Verification (protocols and reports), stability studies (ISO 23640) and transportation tests
- Design History File, STED files and change control.

### Borgensgaard Consulting

Sjælsøparken 4

3450 Blivstrød

charlotte@borgensgaard-consulting.dk

www.borgensgaard-consulting.dk/



**DMD Consulting ApS** is a consultancy specializing in services with respect to fulfilling EU, US and Canadian regulatory requirements concerning Medical Devices, IVD Medical Devices and Quality Management System.

### REGULATORY CONSULTING

- Regulatory Compliance Plan
- Risk Management File
- Technical Documentation (STED file)

### COMPLIANCE

- Design Verification and Validation Software Validation
- Product registration: CE marking, Medical Devices License (CA), 510(k) clearance (USA)

### QUALITY MANAGEMENT

- Quality Management System according to ISO 13485, 21 CFR Part 820 & MDSAP (development and implementation)
- Audits (ISO 13485, 21 CFR Part 820 & MDSAP audits)
- Training (ISO 13485, MDR, Risk Management and Software Validation)

### DMD Danish Medical

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3520 Farum

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www.mddconsulting.eu



**Designpsychology** is a consulting team with specialists in psychology, behavior, and Human Factors who helps companies develop user-friendly medical devices from A-Z. We have a solid foundation in research and many years of experience in product development across medical areas.

### MEDICAL PRODUCT DEVELOPMENT

- Physical Products, Software, and Apps
- Instruction for Use, training videos, and sales material
- User Insights Studies and Behavioural Analyses

### USABILITY ENGINEERING & IEC-62366

- Formative and summative studies
- Task Analysis, Use Specification, and Human Factors input for the risk analysis
- Expert reviews and heuristic evaluations

### UX CLAIMS AND HEALTH ECONOMIC VALUE PROPOSITIONS

- Effect studies and benchmark analyses as documentation and evidence for claims
- Market access strategy with UX differentiation
- Health Technology Assessment and Reimbursement Premium Pricing Strategy

### Designpsykologi A/S

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1801 Frederiksberg C

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kontakt@designpsykologi.dk  
www.designpsykologi.dk





**Devote Consulting** supports process and digital development for companies within life sciences, pharma, MedTech, SaMD, and biotech. With extensive knowledge of processes, technology, and regulations, Devote assists in implementing innovative solutions that ensure project success.

**PHARMA R&D – FROM EARLY RESEARCH TO CLINICAL TRIALS AND AUTHORITIES**

- Regulatory requirements and health authorities
- Selection and implementation of clinical systems and GxP system validation
- Successful organizational change management

**MEDTECH & SAMD – NAVIGATING THE COMPLEX REGULATORY LANDSCAPE**

- Regulatory requirements for medical devices
- Design and development
- Production, implementation, and maintenance

**SCALING BIOTECH – BUILDING THE FOUNDATION FOR GROWTH AND INNOVATION**

- Preclinical studies
- Data management and documentation
- Laboratory equipment and instruments, as well as IT systems

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 Langebrogade 3F 2nd floor  
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[www.devote-consulting.com](http://www.devote-consulting.com)



**Emendo R&D** provides scientific consultancy specialized within medical devices, combination products, and pharma. We offer a large variety of services ranging from early-stage innovation, verification, design control, and complex project management all with a sustainability edge.

**SCIENTIFIC EXPERTS**

- Specializing in Material/Polymer Science, Bioplastic, Skin Adhesives, Sensors, Coatings, Tests, Microbiology, and Scientific/Medical Evidence
- We support your innovation projects from early stage to launch either as innovation team specialists or as project managers
- Experienced in MDR/Design Control

**R&D EXCELLENCE**

- Leveraging best practice collaboration with national and international R&D teams
- Proficient in Project Management
- Design Control Specialists

**SUSTAINABLE PRODUCT INNOVATION**

- Experts in biobased materials
- Leading carbon footprint reducing development projects focusing on scope 3 reductions
- Conduction of Life Cycle Assessment on product and on portfolio level

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 2150 Nordhavn  
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[www.emendo.com/r-d](http://www.emendo.com/r-d)





**Eurofins Medical Device Testing** is a division of Eurofins Scientific and helps medical device manufacturers document the safety and efficacy of their products by delivering unparalleled testing services to meet regulatory requirements and safety guidelines.

### BIOCOMPATIBILITY, CHEMICAL TESTING & CONSULTING

- ISO 10993: Full suite of testing
- Toxicological Assessment
- Guidance according to ISO standards and regional regulations such as EU MDR (Medical Device Regulation) and US FDA requirements

### MICROBIOLOGY & REPROCESSING

- Bioburden, Endotoxins, Sterility Validations, and Routine
- Environmental Monitoring
- Cleaning/Disinfection/Sterilization Validations

### PACKAGING, MECHANICAL TESTING & SHELF-LIFE TESTING

- Packaging for terminally sterilized medical devices: Requirements for materials, sterile barriers systems, and packaging
- Realtime & accelerated aging and associated tests

**Eurofins BioPharma  
Product Testing Denmark A/S**

Ørnebjergvej 1

2600 Glostrup

T: (+45) 26 86 12 66

[www.eurofins.dk/biopharma-services/](http://www.eurofins.dk/biopharma-services/)



**FORCE Technology** is a technological consultancy and testing house. We combine in-depth knowledge and technological expertise with accredited tests to document the safety and performance of products. We assist with testing and certification, have local laboratories and offices in Denmark, and provide services globally.

### MARKET ACCESS

- Achieve global market access with tests in EMC, electrical safety, cybersecurity, technical audiology and material analysis.

### SUSTAINABLE PRODUCTS

- Get advice on reusable materials, packaging design and life cycle assessment.

### INNOVATION AND TRAINING

- Boost innovation with demo projects, case studies and courses.

**FORCE Technology**

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2605 Brøndby

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[www.forcetechnology.com](http://www.forcetechnology.com)





**IQVIA** specializes in delivering market insights, data, analytics, and compliance solutions to the Life Science and MedTech industries. With approximately 80,000 experts globally and 600 experts in the Nordics, we support the entire journey from concept and idea to market launch.

**MARKET DATA AND TECHNOLOGY**

- Data-driven analysis to ensure commercial success
- Market assessment and access
- Product verification and validation

**REGULATORY INTELLIGENCE AND COMPLIANCE**

- Assistance in ensuring regulatory compliance
- Managing costs associated with launching new products
- eQMS for managing quality, safety, and compliance

**GLOBAL RECALLS AND REAL-WORLD EVIDENCE (RWE)**

- Global product recalls
- Ensuring quality and safety
- Real-world evidence (RWE) analysis

**IQVIA**

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[www.iqvia.com/](http://www.iqvia.com/)



**Medicologic** provides consultancy services to the Medtech, Biotech, and Pharma industries. We ensure high standards of safety and quality throughout the product lifecycle and assist in navigating complex requirements such as ISO 13485, CE marking, and FDA approvals within a regulatory environment.

**STRATEGIC AND REGULATORY CONSULTING**

- Principal Advisor in QA/RA, Drug Delivery, Pharma Development
- Regulatory Affairs, Quality Management, and RA CMC Strategies
- MDR/IVDR Specialist, PRRC, and EU Authorized Representative

**QUALITY MANAGEMENT AND COMPLIANCE**

- ISO 13485, eQMS, and CE Marking
- QMS and Sub-Supplier Audits (Lead Auditors)
- NC/CAPA Process Management and Global Registrations

**CLINICAL AND POST-MARKETING SERVICES**

- Clinical Evaluations and Compliance
- Post-Market Surveillance, Qualification, and Validation

**DOCUMENTATION AND SAFETY**

- Design Control, UDI, and Labelling
- SaMD Compliance, Cybersecurity, and Biosafety

**Medicologic A/S**

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**NHTA** is a Nordic leader in market access, health economics, and real-world evidence, delivering clear, impactful insights that drive market success. With expertise across all major therapeutic areas and a track record of over 200 regulatory submissions, NHTA ensures clients receive actionable recommendations for market entry, pricing, and payer engagement.

#### MARKET ACCESS

- Strategic advisory on regulatory and reimbursement pathways
- Proven expertise in pricing and payer engagement strategies
- Tailored support for rapid and sustainable market entry

#### HEALTH ECONOMICS

- Development of robust economic models to communicate product value
- Comprehensive cost-effectiveness and budget impact analyses
- Decision-support tools designed for healthcare stakeholders

#### REAL-WORLD EVIDENCE

- Real-world data generation to confirm clinical and economic outcomes
- Design and management of observational studies and patient registries
- Evidence integration to inform health policy and expand market access

#### NHTA ApS

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2450 CPH SV  
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www.nhta.com/



**NIRAS** is Denmark's leading independent consultant for the design and operation of Life Science production facilities. We help create a decision-making basis for investments, design buildings and production facilities, ensure compliance with cGxP, and optimize facilities and quality systems.

#### ENGINEERING & PROCESSES

- Facility Design: Manufacturing facilities, laboratories, and cleanrooms
- Optimization: Logistics, supply chain and production optimisation
- Sustainability: Sustainability and Energy Solutions

#### QUALIFICATION & VALIDATION

- Validation: Equipment and Processes Validation
- Software Computer Software Validation, Data Integrity
- Cleanroom: Compliance & Validation

#### REGULATORY AND COMPLIANCE

- Audits and Supplier Management: Internal, supplier audits and supplier qualification.
- Quality Management: QMS optimisation and implementation
- Regulatory Compliance: Technical Documentation, Regulatory pathways and submissions

#### NIRAS A/S

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3450 Lilleroed  
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www.niras.com





**Norner** is a plastics research center located in Porsgrunn, Norway, where we develop sustainable and circular product and packaging solutions for the healthcare industry. Our well-equipped laboratories, process pilots, and mechanical and chemical recycling pilots enable the development of industrially viable solutions.

#### **INDUSTRIAL POLYMER SERVICES IN RESEARCH AND DEVELOPMENT**

- Identification and qualification of medical materials
- Processing and prototyping
- Testing

#### **SUSTAINABLE AND CIRCULAR SOLUTIONS FOR MEDICAL DEVICES AND PACKAGING**

- Design for recycling
- Transition from PVC to polyolefins
- Non-fossil raw materials

#### **TESTING, DURABILITY STUDIES, AND FAILURE ANALYSIS**

- Polymer characterization and extraction studies
- Physical properties testing
- Thermal and climate chamber testing, autoclave compatibility testing

#### **Norner AS**

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3920 Porsgrunn, Norway  
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post@norner.no  
www.norner.no



## Pharma IT

A ProductLifeGroup Company

**Pharma IT** is a one stop consulting shop based in Copenhagen. We provide high quality services to the Life Sciences industry. Our team can assist with technical design & engineering expertise, quality & strategic regulatory compliance support, as well as device vigilance services.

#### **DEVICE DEVELOPMENT**

- Conceptualization, Device Design, Prototyping, and 0-series production
- Design Controls, Requirements Engineering, and Compilation of Technical File
- Verification and validation activities

#### **REGULATORY ADVICE AND DOCUMENTATION**

- Risk Classification, CE Marking, and Clinical Investigations
- Documentation Requirements
- Guidance on Regulatory Path to Market and Post-marketing Requirements

#### **QMS, RISK MANAGEMENT, AND VIGILANCE SUPPORT**

- QMS update and maintenance
- Change Control handling and quality documentation approval
- Adverse Event/Device Effect Monitoring, Incident Reporting, Post-market Surveillance, and Annual Reporting

#### **Pharma IT**

Skelbækgade 2  
1717 København V  
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info@pharmait.com  
www.pharmait.dk/





**P4E QA** is a consulting company specialized within the medical device area with many year's "hands-on" experience for preparation of the complete technical file (DHF) according to authority requirements. P4E QA have lead audit competences according to ISO 13485 and many years experience with risk assessments, equipment validation, design verification, biocompatibility, and usability engineering.

**MEDICAL DEVICE - TECHNICAL FILE**

- Design Planning, Design Input, Design Output, and Design Transfer
- Design Specification, Risk Management, D-Verification, D-Validation, and D-Transfer
- Biocompatibility, Clinical Evaluation, and Regulatory Filing (NB & FDA)

**QMS DEVELOPMENT & COMPLIANCE**

- QMS, ISO 13485:2016 preparation, implementation & certification, and education
- Internal and external audit incl. FDA audit experience
- Vendor Management (supplier qualification incl. auditing)

**EQUIPMENT & PROCESSES**

- Equipment Specification, Risk Analysis, and Vendor Management
- Equipment & Process Validation (DQ, IQ, OQ, PQ)
- Project ManagementPharma4ever

**Pharma4ever QA**

Lautruphøj 1-3  
2750 Ballerup  
T: (+45) 42 12 58 53  
[www.pharma4ever.com](http://www.pharma4ever.com)



**Prevas** will support your development journey from idea to launch in the market and secure you are in-line with the regulatory requirements and standards. Our office in Copenhagen is ISO 13845 certified and capable of driving complete medical device development from our premises.

**DEVELOPMENT**

- Product development of mechanics, software and hardware
- Competences to fully understand the product
- Full support during the entire product life cycle

**QUALITY AND REGULATORY COMPLIANCE**

- Quality Management - Development and management of QMS and with resources playing the role as QA Manager/QA Specialist
- Regulatory Affairs - CE marking and handling of requirements and assurance of traceability
- Risk Management, validation, and verification

**CYBER SECURITY**

- In medical devices: ISO 81001-5-1
- In the organisation: ISO 27001 and ISO 27002
- In the development of secure products: IEC 62443-4-1 and IEC 62443-4-2

**Prevas A/S**

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[www.prevas.dk](http://www.prevas.dk)





**Probatus** delivers expert SaMD and MDSW guidance, specializing in digital health, AI/ML, and compliance (ISO 13485, MDR/FDA). Practical, hands-on experience, and streamlined regulatory navigation optimizes QMS, agile processes and efficient device lifecycle management.

#### SOFTWARE & MEDTECH EXPERTISE (25+ YRS)

- Software lifecycle processes and documentation tailored for Medical Devices
- Risk management and validation tailored for Software Medical Devices
- Expertise in software, digital health, e-health/m-health, AI/ML, and interoperability

#### REGULATORY ADVISORY

- Regulatory strategies for connected and intelligent devices
- Software Development Lifecycle Compliance
- Regulatory advisory and documentation

#### QUALITY MANAGEMENT & AUDITING

- Design and implementation of QMS tailored AI and SaMD development (ISO 13485/42001)
- Certified 13485 Lead Auditor
- Continual improvement and efficient Change Management

#### Probatus ApS

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2765 Smørum

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**Qmed Consulting** is a consultancy firm and a full-service Contract Research Organization (CRO) offering services to clients developing and marketing medical devices. We provide expertise in regulatory strategy, clinical trials, and market access, including CE marking and FDA approval of medical devices, as well as defining the reimbursement pathway for the client's product at the national level.

#### CLINICAL TRIALS

- Strategic planning of clinical trials
- Setup and management of clinical trials and performance tests
- Monitoring of clinical trials

#### MARKET ACCESS

- Market analysis
- Commercial due diligence
- Reimbursement analysis

#### QA AND REGULATORY AFFAIRS

- Implementation of quality systems in compliance with MDR and ISO 13485
- Design control and product approvals
- Technical documentation

#### Qmed Consulting A/S

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1150 Copenhagen K

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www.qmed-consulting.com/





**RSDU**  
CONSULTING

**RSDU Consulting** are Risk Management specialists within MDR/IVDR/FDA, and ISO14971. We provide consulting with a focus on cross-functional cooperation with your experts in e.g. Biological Evaluation, Usability, and Post Market Surveillance to secure compliance with relevant regulations.

**REGULATORY SUPPORT:**

- Review/consulting for Risk Management File with a focus on Audit
- Risk Management concerning QMS and if required ERM
- New/review/update: Processes, Procedures, templates, methods

**RISK MANAGEMENT SUPPORT:**

- Trace within the Risk Management File and QMS
- Link to usability, Biological Evaluation, PMS, and other regulatory-required areas
- Production: Design/Production/Assembly FMEAs

**RISK MANAGEMENT ACTIVITIES:**

- Risk Management workshops
- Training organization in Risk Management ISO14971
- Updating/Building Risk Management Files

**RSDU Consulting Aps**

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**Sander Consult** provides RA assistance within medical devices and combinations products. The primary focus is to help manufacturers and other EU economic operators and stakeholders through the intricate regulatory landscape as relevant for product documentation and submissions.

**SERVICES WITHIN REGULATORY AFFAIRS**

- Compliance with EU MDR requirements and other relevant regulations and guidelines
- Technical documentation e.g. for high-risk products
- Regulatory intelligence and training

**DRUG-DEVICE COMBINATIONS**

- Product classification, borderline products and drug-device demarcation
- Pre-submission meetings and product approval submissions
- Competent authority and notified body dialog

**REGULATORY AFFAIRS SUPPORT**

- Day-to-day on site/off site regulatory support and life cycle management
- Notified body and competent authority submissions
- Notified body dialog pre and post EC certification

**Sander Consult ApS**

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**Technolution** is a growing consultancy within Pharma and MedTech developing innovative and life-improving medical devices from ideation to realization. As an integral part of MGS Mfg. Group, our offerings enable seamless integration with tooling and high-volume manufacturing.

## HEALTHCARE PRODUCT EXPERTISE

- Experienced in a wide range of products with a track record of more than 250 successful projects based on a track record during 20+ year

## ONE-STOP-SHOP

- With all areas of expertise needed for handling a full project, we offer end-to-end development ensuring compliance with both regulatory requirements and user inputs

## REDUCED RISK AT HIGH SPEED

- A unique approach based on our experience in developing complex medical devices and obtaining faster speed-to-market at reduced risk

## Technolution

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www.technolution-tn.com/



**The Danish Technological Institute** serves as a crucial bridge between research and Danish industry, including the medical device sector. The Institute transforms new knowledge and technology into value for its clients through the improvement of products, materials, processes, and organizational structures.

## INNOVATION AND DEVELOPMENT

- Medical technology research and development projects
- Materials technology and concept development
- Health data, health technology, and welfare technology

## MARKET APPROVAL

- Technical documentation of medical devices
- Accredited testing, analysis, and transport testing
- Stability studies and functional testing

## OPTIMIZATION AND QUALITY ASSURANCE IN PRODUCTION

- Consultation on material and supplier changes
- Support for failure analysis and ongoing quality control
- Production technology and process automation

## Teknologisk Institut

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# **An industry association for more than 230 of Denmark's leading MedTech companies**

MedTech Denmark is the industry association for companies in Denmark which develop, manufacture, and sell medical devices. The goal of MedTech Denmark is to strengthen the ability for more than 230 member companies to operate in the Danish Market. We do so by working closely with political decision makers, the healthcare system and the research institutes to closely monitor the needs, demands, and challenges in the Danish healthcare sector and to offer solutions where needed.

MedTech Denmark provides counseling, network opportunities, and education to members to strengthen their ability to develop and sell medical devices and to comply to the regulatory framework of the sector.

On an international level, MedTech Denmark actively contributes to the European sister organization, MedTech Europe.

## **Medicoindustrien**

Bøge Alle 5

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[www.medicoindustrien.dk](http://www.medicoindustrien.dk)