

A photograph of a male and female medical professional in a hospital hallway. The man, on the left, is wearing a white lab coat over a blue shirt and a striped tie, with a stethoscope around his neck. He has his arms crossed and is looking towards the camera with a slight smile. The woman, on the right, is also wearing a white lab coat and has blonde hair. She is holding a clipboard and looking towards the camera with a smile. The background is a bright, out-of-focus hospital hallway.

# **”Ny” lovgivning for medicinsk udstyr**


*- hvorfor er det vigtigt for det offentlige/private samarbejde?*

# WHO ARE WE?

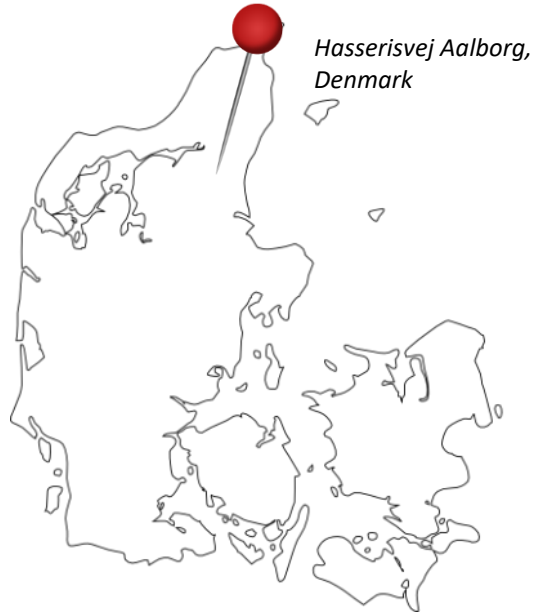
- OUR DYNAMIC TEAM IS FOCUSED ON DEVELOPMENT AND IMPLEMENTATION OF SPECIALIZED HEALTHCARE IT SOLUTIONS



**Mads Lause Mogensen** *M.Sc., Ph.D.*

Chief Executive Officer (CEO) 

[mm@treatsystems.com](mailto:mm@treatsystems.com)



*Treat Systems is part of  
the Judex/Amphi family*



# SERVICES AND QUALIFICATIONS

- HIGH PERFORMANCE TEAM

Treat Systems is a dynamic and innovative Danish SME focused on developing certified healthcare software solutions including decision support, machine learning (ML) and artificial intelligence (AI). Our current key clinical focus areas are within infectious diseases, microbiology, antibiotic therapy and antibiotic resistance.

- Decision support
- Physiological models
- Machine learning
- Scientific connections to Universities
- Cost-benefit analysis
- Artificial intelligence
- Causal probabilistic (Bayesian) networks

Modelling



- Infectious diseases
- Workflow analysis
- Microbiological and pathological understanding
- Clinical Trails
- Antimicrobial Stewardship
- Sepsis
- Infection control and surveillance

Clinical understanding



- ISO 13485 – Quality Management System
- ISO 62304 – Software life-cycle processes
- ISO 14971 – Risk Management
- ISO 27001 – Information security
- ISO 27701 – Privacy
- ISO 62366 – Usability
- ISO 14155 – Clinical Investigation

Regulatory compliance



- Multi language programming (C#, Angular, C++, JAVA, VBA)
- Web based technologies
- SQL or InterSystems Caché database structure
- Integration to hospital systems e.g. HL7 or FHIR
- Statistical analysis (SPSS, R, Excel, Matlab)

Technologies



# BLACK BOX MODELLING

TRADEOFF BETWEEN PERFORMANCE AND TRANSPARENCY

You should use visual graphic that supports interpretation of the algorithm's results



- ❑ The disadvantage of advanced AI models is that it can be difficult for humans to see how the model has arrived at a given outcome.

# AI IS A TOOL

*IT IS ALL ABOUT SELECTING THE PROBER TOOL*



# KEY TECHNOLOGIES

WE HAVE FALLEN IN LOVE WITH BAYESIAN NETWORKS AND COST-BENEFIT

## Artificial intelligence (AI)

### Machine Learning

### Deep Learning

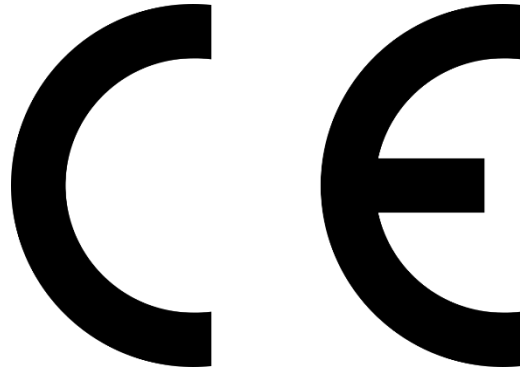
- Deep Neural Network (DNN)
- Convolutional Neural Network (CNN)
- Artificial neural networks
- Decision trees
- Support vector machines
- **Bayesian networks**
- Genetic algorithms
- Reasoning
- Knowledge representation
- Planning
- Learning
- Natural language processing
- Perception
- **Cost-benefit**



# REGULATIONS AND LEGAL

*IS MY SOFTWARE TOOL OR APP A MEDICAL DEVICE?*

The answer to this question is all based on its intended use and the claims. It shall be for **diagnostic, treatment, prognosis** and **prevention** purposes for the individualized patient



Placing software medical device on the European market is a long and expensive journey with lots of obstacles and long detours.

# AN EXAMPLE OF MEDICAL EQUIPMENT

IS MY SOFTWARE TOOL OR APP A MEDICAL DEVICE?

- ❑ Purpose / intended use, defined on the basis of:
  - What the product does (Purpose)
  - Where to use the product (Application environment)
  - Who should use the product (Users)
  - How the product achieves its effect (Functionality)
- ❑ Claims
- ❑ Marketing materials



Tongue depressor

VS.



Ice spin



# CLASSIFICATION RULES - MDR

- ❑ Software is now classified as an “active device”
- ❑ The important rule for TREAT is Rule 11 (Annex VIII, Chapter 3 of MDR)

L 117/144

EN

Official Journal of the European Union

5.5.2017

---

## 6.3. Rule 11

Software intended to provide information which is **used to take decisions with diagnosis or therapeutic purposes** is classified as class IIa, except if such decisions have an impact that may cause:

- death or an irreversible deterioration of a person’s state of health, in which case it is in class III; or
- a serious deterioration of a person’s state of health or a surgical intervention, in which case it is classified as class IIb.

Software intended to **monitor physiological processes** is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb.

All other software is classified as class I.

# TREAT-ESSENTIAL

- THE CLINICIAN DECIDES THE DIAGNOSE(S) AND CAN GET HELP WITH PATHOGEN DISTRIBUTION, LOCAL SUSCEPTIBILITIES AND ANTIBIOTIC TREATMENT

- TREAT Essential is a system that can generate personalized antimicrobial advice bedside within a minute.
- The solution provides a great overview of infection relevant information
- The solution automatically calculates the severity of the infection
- It only requires the diagnosis to be input by the clinician, along with some intelligent follow up questions about symptoms and findings and background information.
- If the doctor wants to see the reasoning behind the personalized and rational antibiotic advice the “Advanced decision support” can be expanded

The screenshot displays the TREAT-ESSENTIAL interface for a patient named Edward (INFECTIONOUS) Teach, a 50-year-old male. The interface is divided into several sections:

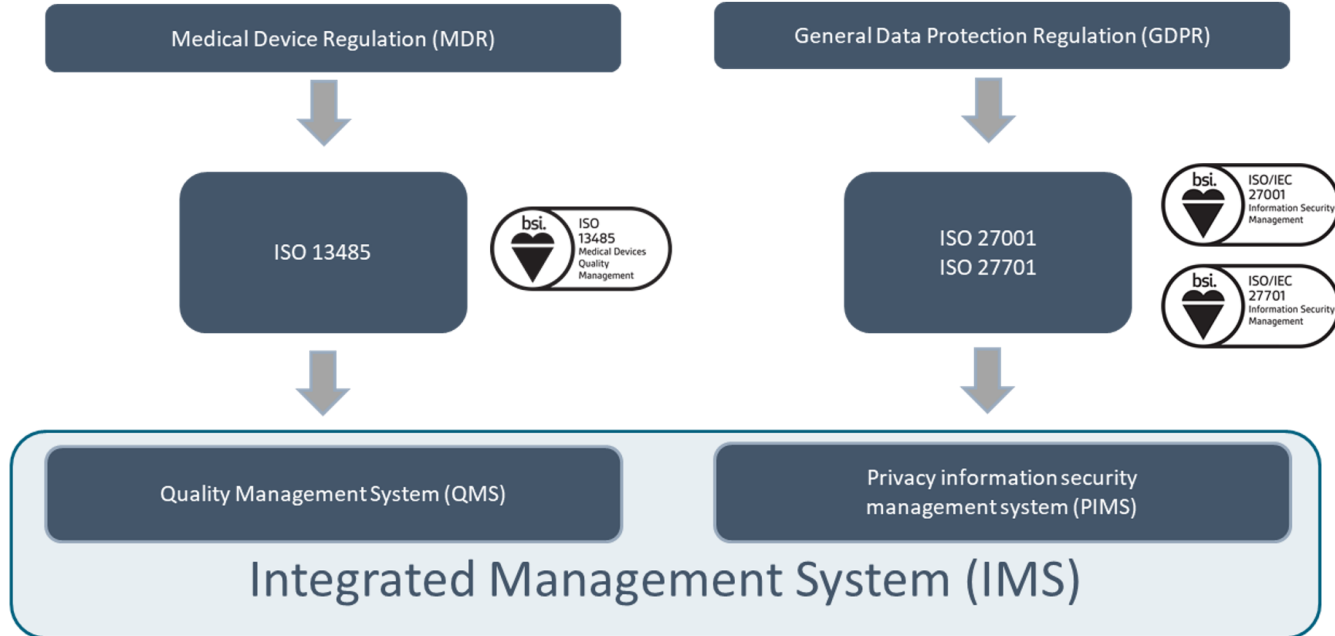
- Patient Data:** Includes ABX treatment history (Ampicillin on 24-08-2019, Vancomycin on 01-09-2019) and Antibiotic Allergy information.
- Infection severity scores:** Shows qSOFA score: 0 (2 of 3 measured) and CURB65: 0 (3 of 6 measured), resulting in a **Moderate** severity level.
- Diagnoses:** A human silhouette with various body systems highlighted: Nervous system, Lower respiratory tract (highlighted in orange), Urinary tract, Genital/Sexually transmitted, Bone and joints, Ophthalmic, Ear nose throat, Cardiovascular, Abdomen/GI, and Skin and soft tissue. A search bar and filters for Surgical site, Tropical and endemic, and Unknown source/Primary are also present.
- Recommended treatment:** The system recommends **Levofloxacin PO**. The selected treatment is Levofloxacin(Oral).
- Advanced decision support:** This section is expanded and shows three charts:
  - Most prevalent pathogens:** A bar chart comparing 'All coverage' (green) and 'In-vivo covered' (red) for various pathogens like Streptococcus Pneumoniae, Viruses, Haemophilus, Mycoplasma, Chlamydia, Legionella, Staphylococcus Positive, and Escherichia Coli.
  - Total in-vivo coverage:** A bar chart comparing 'Total in-vivo coverage' for Levofloxacin PO against other antibiotics like Amoxicillin and Doxycycline.
  - Cost-Benefit:** A bar chart comparing 'Total cost benefit' for Levofloxacin PO against other antibiotic regimens.

# STATEMENT OF INTENDED USE

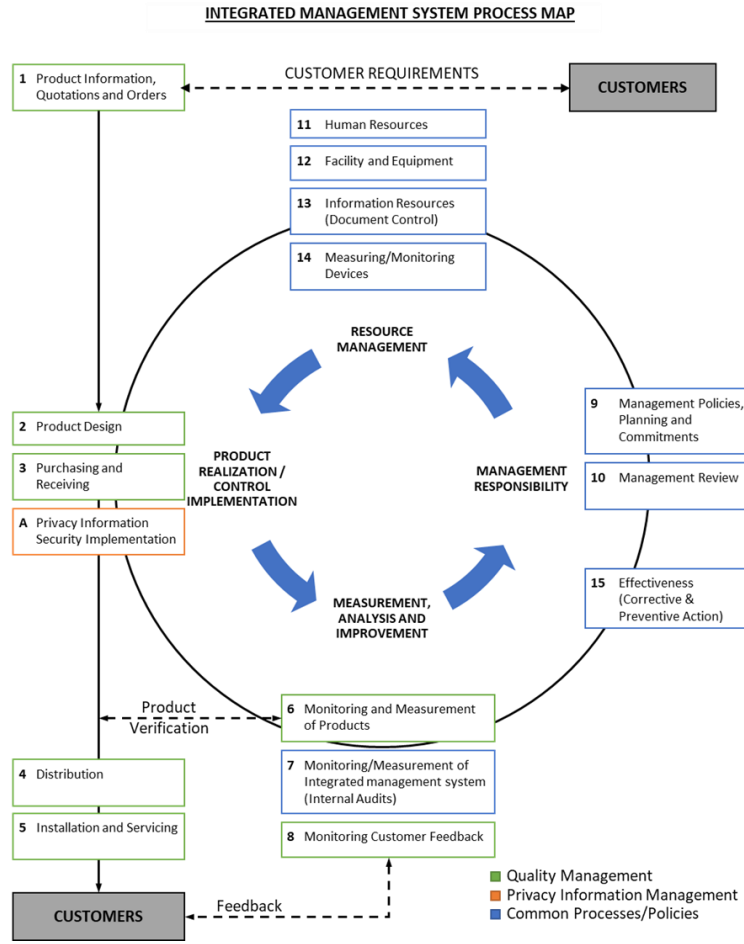
- TREAT-Essential is a stand-alone software product intended to be used to **provide decision support** for guiding hospital physicians on severity of illness, diagnosis, presence of pathogens and choice of antibiotic treatment for bacterial infections. Guidance is provided on the basis of patient demographics, background conditions, vital signs, laboratory test results, symptoms and signs relevant to infection, radiological and microbiological results.
- TREAT-Essential is also intended to be used to **provide advice** on the optimal dosage of antibiotic treatments, based on patient-specific factors such as demographics, renal and hepatic function.
- TREAT-Essential is also intended to be used to generate **personalised** antibiograms to show an estimate of the in-vivo susceptibilities for given antibiotic-bacteria combinations, based on patient-specific factors.

# QUALITY MANAGEMENT AND PRIVACY INFORMATION SECURITY

- Treat Systems has designed and implemented an integrated management system (IMS), covering both quality- and privacy information management (QMS and PIMS), in order to better satisfy our customer's needs, to ensure product quality, and to improve the management of our company. The IMS is designed to fulfil the requirements of the international standards ISO 13485, ISO 27001 and ISO 27701, and to ensure compliance with the Medical Device Regulation (EU) 2017/745 (MDR), the General Data Protection Regulation (EU) 2016/679 (GDPR) and local jurisdictional requirements.

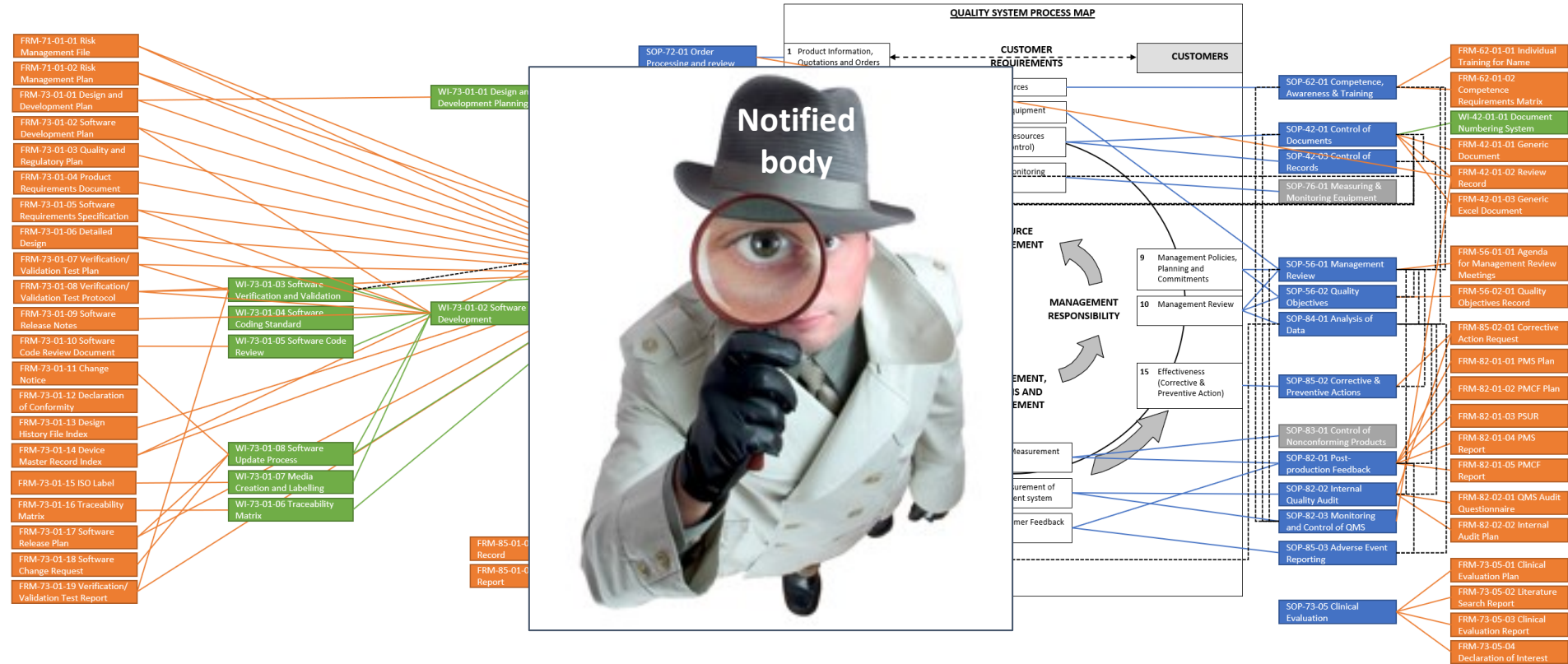


# INTEGRATED MANAGEMENT SYSTEM PROCESS MAP



# PROCEDURES, WORK INSTRUCTIONS AND TEMPLATES/RECORDS

- INSPECTION BY THE NOTIFIED BODY



# OVERVIEW OF THE TECHNICAL DOCUMENTATION

## Technical file

### Design history file (DHF)

- **Planning** (Quality/Regulatory planning and rationale, design/dev planning)
- **Design Input** (Customer/Product Requirements)
- **Design Output** (Design and detailed design documents, IFU etc)
- **Design Review** (Review docs)
- **Design Verification** (Test plans, protocols, reports for each release)
- **Design Validation** (Test plan, protocol for customer site validation)
- **Design Transfer** (Process for creating device master record, DMR index)
- **Design Changes** (Release history and release plans, notes for each release)
- **Risk Management** (Risk management plan, risk file and risk mitigation/fallback procedures for communication to the customer, as appropriate)

### Device master record (DMR)

- **Device specifications** - software, database architecture, software configuration items, description of external interfaces
- **Location/specification** of software source code/binaries
- **Installation files** - maintenance and servicing information including IFU, installation instructions, installer files, configurations/settings
- **Risk management** - documentation for the customer

### Clinical evaluation

- **Clinical evaluation plan** - General safety and performance requirements, Intended target groups, Intended clinical benefit, Clinical safety, determination of benefit-risk ratio, clinical investigation plan
- **Literature search report** - Research questions, literature search methodology, data source, analysis and appraisal plan, search results
- **Clinical evaluation report** - Clinical background, state of the art, device under evaluation and conclusion

### Post marked surveillance

- **Post market surveillance plan** – when completed, forms the basis of the PMSS for the device
- **Periodic safety update report (PSUR)** – required for Class IIa+, frequency of 2 years for IIa, 1 year for IIb+
- **Post market surveillance report** – equivalent of PSUR but for Class I devices, fewer requirements
- **Post market clinical follow up plan** – describes the ongoing data collection and analysis process
- **Post market clinical follow up report** – included in updates to the clinical evaluation
- **Risk management plan** – describes the extent of risk management activities
- **Risk management file** – compilation of all risks, mitigations etc.



# IMPLEMENTATION OF THE QMS

## Visual Studio



Azure DevOps

Requirements

Tests cases

Risks

Backlog items

Developer tasks

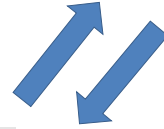
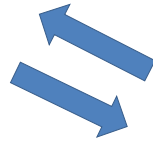
Releases

Defects/  
Bugs

Change  
request



SharePoint



Other tasks handled in DevOps:

Automatic code  
review

Manual code  
review

Automatic code  
coverage/unit tests

Automatic vulnerability  
and security tests



# REGULATIONS ABOUT FOR IN-HOUSE MANUFACTURING

(MDR ARTICLE 5(5))

## Article 5

### Placing on the market and putting into service

1. A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.
2. A device shall meet the general safety and performance requirements set out in Annex I which apply to it, taking into account its intended purpose.
3. Demonstration of conformity with the general safety and performance requirements shall include a clinical evaluation in accordance with Article 61.
4. Devices that are manufactured and used within health institutions shall be considered as having been put into service.
5. With the exception of the relevant general safety and performance requirements set out in Annex I, the requirements of this Regulation shall not apply to devices, manufactured and used **only within health institutions** established in the Union, provided that all of the following conditions are met:
  - (a) the devices are **not transferred** to another legal entity,
  - (b) manufacture and use of the devices occur under appropriate **quality management systems**,
  - (c) the health institution justifies in its documentation that the **target patient group's specific needs cannot be met**, or cannot be met at the appropriate level of performance by an **equivalent device available on the market**,
  - (d) the health institution provides information upon request on the use of such devices to its competent authority, which shall include a justification of their manufacturing, modification and use;

- (e) the health institution draws up a declaration which it shall make publicly available, including:
  - (i) the name and address of the manufacturing health institution;
  - (ii) the details necessary to **identify the devices**;
  - (iii) a declaration that the devices meet the **general safety and performance requirements** set out in Annex I to this Regulation and, where applicable, information on which requirements are not fully met with a reasoned justification therefor,
  - (f) the health institution draws up **documentation** that makes it possible to have an understanding of the manufacturing facility, the manufacturing process, the design and performance data of the devices, including the intended purpose, and that is sufficiently detailed to enable the competent authority to ascertain that the general safety and performance requirements set out in Annex I to this Regulation are met;
  - (g) the health institution takes all necessary **measures to** ensure that all devices are manufactured in accordance with the documentation referred to in point (f), and
  - (h) the health institution **reviews experience** gained from clinical use of the devices and takes all necessary corrective actions.

Member States may require that such health institutions submit to the competent authority any further relevant information about such devices which have been manufactured and used on their territory. Member States shall retain the right to restrict the manufacture and the use of any specific type of such devices and shall be permitted access to inspect the activities of the health institutions.

This paragraph shall not apply to devices that are manufactured on an industrial scale.




Quality management system + Full technical file



Open  
For  
Discussion

Mads Lause Mogensen *M.Sc., Ph.D.*

Chief Executive Officer (CEO) 

[mm@treatsystems.com](mailto:mm@treatsystems.com)

+45 25484439