



MEDICAL DEVICE SEMINAR DAYS

EMPOWERING INNOVATION IN THE MEDICAL DEVICE INDUSTRY

Keynote Presentations by Industry Leaders · Speed Consulting
Sessions with Regulatory Experts · Case Studies and Best
Practices · Meet the Expert Networking Dinner

24 - 25 FEBRUARY 2026

9:00 - 17:15 CET



MEET THE EXPERT NETWORKING DINNER



HOLIDAY INN MUNICH, GERMANY

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SEMINAR LANGUAGE: ENGLISH

 **HOLIDAY INN MUNICH - WESTPARK, ALBERT-ROSSHAUPTER-STRASSE 4, 81369 MUNICH**

Introduction

The Eurofins Medical Device Seminar is an essential forum for professionals engaged in the medical device industry, focusing on the latest advancements and regulatory requirements. This seminar will provide a comprehensive overview of regulatory topics and recent updates in medical device regulations. Participants will benefit from expert-led presentations and interactive speed consulting sessions, designed to offer tailored advice on compliance and strategic implementation. This event is an invaluable opportunity for professionals to deepen their understanding of regulatory frameworks, enhance their strategic approach, and network with industry leaders. We invite you to join us for this informative and engaging seminar to stay at the forefront of medical device innovation and regulation.

Why attend?

Join leading experts and professionals in the medical device industry for two days of insightful presentations, interactive consulting sessions, and valuable networking opportunities. Stay ahead of regulatory changes and gain practical knowledge to drive your business forward.

Agenda Highlights

- Keynote Presentations by Industry Leaders
- Speed Consulting Sessions with Regulatory Experts
- Case Studies and Best Practices
- Meet the Expert Networking Dinner

Who Should Attend

- QA/RA managers
- product developers
- regulatory affairs professionals

Registration

Early Bird Discount Available Until 24 November 2025

Registration Fee: VAT Excluded

EarlyBird: € 699 (until November 24, 2025)

Regular: € 849

Seminar Language: English

Register here:

<https://form.jotform.com/251033321340438>



The price includes: participation in the workshop, lunch and refreshments.

You will receive confirmation, payment and invoicing details by email after submission. The registration fee is payable in advance by bank transfer.

09:00 - 09:30

Welcome and introduction

Dr. Peter Havel, Eurofins Medical Device Services

09:30 - 10:15

MDR compliant implant production at the point of care

Daniel Seiler, POC APP AG

10:15- 11:00

Understanding the FDA Draft Guidance Chemical Analysis for Biocompatibility Assessment of Medical Devices

Jan Peeters, Peeters MD Consulting

11:00 - 11:30

Coffee break

11:30 - 12:15

Risk based R&D approaches for medical devices

Dr. Michaela Hajek, 3R LifeScience GmbH

12:15 - 13:00

Risk Management according to ISO 14971 – The All-over Reference Standard

Jana Osterritter, Eurofins Medical Device Consulting

13:00 - 13:45

Lunch

1st Round Speed Consulting Sessions

15 Minute overview & 75 Minute open discussion

13:45 - 15:15

I The Post Market Surveillance: Regulatory requirements & practical implications

Margherita Miccheli, Eurofins Medical Device Consulting

II Regulatory requirements FDA vs EU

Yana Katsman, Eurofins Medical Device Consulting

III Quality Management - Beyond Compliance: Engaging with ISO 13485 in Real-World Contexts

Jana Osterritter, Eurofins Medical Device Consulting

IV Some Challenges for Compliance with FDA Draft Guidance Chemical Analysis

Jan Peeters, Peeters MD Consulting

V Digital tool for risk based project planning

Dr. Ing. Janin Leuckert, 3R LifeScience GmbH

15:15 - 15:45

Coffee break

2nd Round Speed Consulting Sessions

15 Minute overview & 75 Minute open discussion

I The Post Market Surveillance: Regulatory requirements & practical implications

Margherita Miccheli, Eurofins Medical Device Consulting

II Regulatory requirements FDA vs EU

Yana Katsman, Eurofins Medical Device Consulting

15:45 - 17:15

III Quality Management - Beyond Compliance: Engaging with ISO 13485 in Real-World Contexts

Jana Osterritter, Eurofins Medical Device Consulting

IV Some Challenges for Compliance with FDA Draft Guidance Chemical Analysis

Jan Peeters, Peeters MD Consulting

V Digital tool for risk based project planning

Dr. Ing. Janin Leuckert, 3R LifeScience GmbH

19:00

Meet the Expert & Networking Dinner Event

Please note: The agenda and topics for the Medical Device Seminar is subject to change.

09:00 - 09:30

Welcome and introduction

Dr. Peter Havel, Eurofins Medical Device Services

09:30 - 10:15

Top 10 Auditor Findings in Biocompatibility Evaluation Files for Gas Pathways: How to Overcome Them and Comply with the 2024 Updates Jacqueline van Druten, Clin-r

10:15- 11:00

Regulatory Crossroads: Navigating New Hurdles for Medical Devices in Switzerland

Beat Keller, SMDC Swiss Medical Device Consulting GmbH

11:00 - 11:30

Coffee break

11:30 - 12:15

New approach methods for medical devices

Dr. Helge Gehrke, Eurofins Medical Device Testing

12:15 - 13:00

The Bible of Biocompatibility ISO 10993-1 – Important changes and how to deal with them

Marcel Dörkes, Eurofins Medical Device Consulting

13:00 - 13:45

Lunch

1st Round Speed Consulting Sessions

15 Minute overview & 75 Minute open discussion

I

Packaging validation, ageing and accelerated ageing

Lisa Heilemann, Eurofins Medical Device Sterile Packaging

II

General Safety and Essential performance of electrical medical devices – IEC 60601-1 Series

Nael Haj Rachid, Medical Device Safety Testing

13:45 - 15:15

III

Insights into in vitro Hemocompatibility testing according to ISO 10993-4

Torben Gehring, Eurofins Medical Device Testing

IV

Change Assessment in the context of ISO-10993-1 revision

Marcel Dörkes, Eurofins Medical Device Consulting

V

Digital tool for a technical documentation

Dr. Michaela Hajek, 3R LifeScience GmbH

15:15 - 15:45

Coffee break

2nd Round Speed Consulting Sessions

15 Minute overview & 75 Minute open discussion

Packaging validation, ageing and accelerated ageing

I Lisa Heilemann, Eurofins Medical Device Sterile Packaging

Introduction to IEC 60601-1:

II Ensuring Safety in Medical Devices

Nael Haj Rachid, Medical Device Safety Testing

III Insights into in vitro Hemocompatibility testing according to ISO 10993-4

Torben Gehring, Eurofins Medical Device Testing

IV Change Assessment in the context of ISO-10993-1 revision

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Dr. Michaela Hajek, 3R LifeScience GmbH

15:45 - 17:15

Abstracts - 24th February

MDR compliant implant production at the point of care

Daniel Seiler, POC APP AG

New technologies, such as 3D printing, have revolutionised surgical practices, allowing for precise and personalised patient care. In 2022, the University Hospitals in Basel and Salzburg initiated a PEEK (polyetheretherketone) 3D printing process for patient-specific cranial implants technically and regulatory supported by POC APP. This presentation gives an overview of the implementation of the end-to-end production process under MDR 2017/745 Article 5/5 and the outcomes during its first year

Understanding the FDA Draft Guidance Chemical Analysis for Biocompatibility Assessment of Medical Devices

Jan Peeters, Peeters MD Consulting

In September 2024 US FDA issued the draft guidance “Chemical Analysis for Biocompatibility Assessment of Medical Devices”. The document outlines a structured approach to chemical characterisation in alignment with ISO 10993-18:2020. It emphasises standardised practices for extraction, analysis, and reporting to improve the quality of analytical data. Such reliable data can be used to omit certain in vivo and in vitro biological tests.

Risk based R&D approaches for medical devices

Dr. Michaela Hajek, 3R LifeScience GmbH

This presentation deals with typical challenges in R&D projects and provides solutions on how to manage and control project risks as well as the completeness of the required development documentation. Attendees will learn that project planning is not equivalent with development planning, proactive dealing with unforeseen events is as well as essential as planning and controlling of the Design History File. The session also points out how this continuously increasing development complexity can be digitally managed to ensure product and documentation compliance.

Risk Management according to ISO 14971 – The All-over Reference Standard

Jana Osteritter, Eurofins Medical Device Consulting

ISO 14971 is the central standard for risk management in the development and lifecycle of medical devices – and a fundamental reference for numerous other international regulations and standards. This session provides a structured overview of ISO 14971, focusing on its core concepts, terminology, and practical application. Key topics include risk analysis, risk evaluation, risk control, and the integration of benefit-risk considerations. We will also examine how ISO 14971 interfaces with standards such as ISO 13485, ISO 10993, IEC 62366, and IEC 60601. Through real-world examples and insights, attendees will develop a clear understanding of how to implement effective and compliant risk management processes that go beyond mere documentation.

The Post Market Surveillance: Regulatory requirements & practical implications

Margherita Miccheli, Eurofins Medical Device Consulting

Upon the entry into force of the European Medical Device Regulation (MDR), the implementation of an effective Post-market surveillance system, proportionate to the risk class and appropriate for the type of device, has become a pivotal requirement for manufacturers. This session will provide an in-depth understanding of the key requirements, concepts, and the overall process for post-market surveillance under the MDR and the implications of applicable MDCGs, offering valuable insights and practical guidance for adapting your internal procedures and ensuring medical device compliance with MDR requirements.

Quality Management - Beyond Compliance: Engaging with ISO 13485 in Real-World Contexts

Jana Osteritter, Eurofins Medical Device Consulting

This session offers a focused introduction to the key principles and structure of ISO 13485, the internationally recognised quality management standard for medical devices. We will briefly revisit the standard's core requirements, its alignment with regulatory expectations, and its role in risk-based thinking. The main emphasis of the session, however, lies in the subsequent open discussion. Attendees are invited to share challenges, solutions, and practical experiences with ISO 13485 implementation. Whether you're refining existing systems or navigating audits and regulatory updates, this exchange aims to go beyond theoretical compliance and explore how ISO 13485 functions in real-world environments.

Some Challenges for Compliance with FDA Draft Guidance Chemical Analysis

Jan Peeters, Peeters MD Consulting

Chemical analysis of medical devices is typically conducted by evaluating the extractable and leachable profiles of the test article following an extraction process. A major challenge lies in designing extraction conditions that align with the expectations of the US FDA, particularly in light of the draft guidance “Chemical Analysis for Biocompatibility Assessment of Medical Devices”. The session will be conducted as an open discussion focusing on key considerations regarding the design of extraction procedures and their regulatory acceptability.

Digital tool for risk based project planning

Dr. Ing. Janin Leuckert, 3R LifeScience GmbH

This session outlines that off-the-shelf project planning tools are useful but not sufficient as they react on unforeseen events but do not reflect them. We exchange ideas on digital solutions to manage and control project activities, times and costs. Participants will understand that controlling is not only needed in company's financial context, but that risk-based planning is crucial for every project - whether in product development or product change projects or even for strategic company management.

Abstracts - 25th February

Top 10 Auditor Findings in Biocompatibility Evaluation Files for Gas Pathways: How to Overcome Them and Comply with the 2024 Updates

Jacqueline van Druten, Clin-r

This talk explores the top 10 most common auditor findings in Biocompatibility Evaluation Files for gas pathways, with a focus on both FDA and EU Notified Body expectations. It highlights the impact of the 2024 updates to the ISO 18562-series and recent changes to ISO 10993-17 and 10993-18, offering practical strategies to navigate evolving requirements. Attendees will learn how these updates influence gas pathway risk assessments and toxicological evaluations, particularly under EU MDR. The session will also outline essential documentation for a complete Biological Evaluation File and provide proactive solutions to prevent regulatory delays and streamline compliance in 2024 and beyond.

Regulatory Crossroads: Navigating New Hurdles for Medical Devices in Switzerland

Beat Keller, SMDC Swiss Medical Device Consulting GmbH

Since Mai 2021, Switzerland is no longer part of the European Single Market for medical devices, as the Mutual Recognition Agreement (MRA) between Switzerland and the EU was not updated. Although Switzerland continues to unilaterally recognise the CE mark, manufacturers face additional regulatory hurdles when placing CE-marked products on the Swiss market. The first part of the presentation will outline these challenges and explain how to overcome them. The second part will explore the current status of FDA approval recognition in Switzerland and provide insights into what developments can be expected in the (near) future.

New Approach Methods for Medical Devices – Shifting from Animal Studies to In Vitro Studies for more Comprehensive Data and Ethical Research

Dr. Helge Gehrke, Eurofins Medical Device Testing

The transition from animal studies to in vitro methods in medical device testing, coupled with growing regulatory acceptance, is becoming evident and will likely change future testing designs and requirements. Endpoints such as irritation, sensitization, and pyrogenicity testing, which are currently addressed using animal testing, will be replaced by in vitro testing. Therefore, this session will explore existing and new developments in testing for irritation and sensitization, as well as comparisons with traditional animal testing. Strategies for selecting the appropriate in vitro tests will be presented, along with case studies that demonstrate challenges, pitfalls, and solutions. Changes in regulatory acceptance as well as updated from the ISO working groups will be presented.

The Bible of Biocompatibility ISO 10993-1 – Important changes and how to deal with them

Marcel Dörkes, Eurofins Medical Device Consulting

This presentation covers the latest changes included in the ISO 10993-1 standard for the biological safety evaluation of medical devices. An overview of key aspects that are going to be implemented will be provided, along with an explanation of their practical significance. A major focus will be on the identification and assessment of biological risks associated with the categorisation of medical devices and the general outline and processes of the biological risk assessment as described in the new version of the standard.

Insights into in vitro Hemocompatibility testing according to ISO 10993-4

Torben Gehring, Eurofins Medical Device Testing

In this session, a comprehensive overview of hemocompatibility testing procedures will be provided. In this session, we will explore comprehensive strategies for hemocompatibility testing, focusing on critical aspects such as sample preparation, extraction conditions, and data interpretation. We will also address the challenges and pitfalls associated with hemocompatibility testing, particularly the differences between static and dynamic conditions. Emphasis will be placed on the need to simulate clinical conditions to enhance the relevance and reliability of the test outcomes. This session aims to provide a thorough understanding of the complexities involved in hemocompatibility testing and offer practical solutions to common issues encountered in the process.

Change Assessment in the context of ISO-10993-1 revision

Marcel Dörkes, Eurofins Medical Device Consulting

In this session, the latest changes to the ISO 10993-1 standard for the biological evaluation of medical devices will be covered in detail. We will discuss the practical implications of these changes and how to handle them effectively. General approaches for the change assessment covering new aspects of the underlying guidance will be discussed. We will explain what procedures shall be followed for different devices and certification phases and how the impact on available biological safety documentation can be handled. In addition, sufficient time will be included to cover open discussion on practical aspects with the participant on recent hurdles in the context of the biological safety assessment.

Digital tool for a technical documentation

Dr. Michaela Hajek, 3R LifeScience GmbH

This session is about challenges in generating, completing and maintaining of MDR compliant Technical Documentation. We discuss about solutions to digitally structure and manage the continuously increasing documentation complexity in product development and product changes. Attendees will understand that the Technical Documentation is not a regulatory must-have, but rather an extraction of the entire product knowledge, which serves as the key to the product life cycle management and to new generations.

STAY TUNED FOR UPDATES ON THE AGENDA, ABSTRACTS AND OUR SPEAKERS!

Speakers - in alphabetical order



JACQUELINE VAN DRUTEN

CLIN-r+

Jacqueline van Druten (MICR.CIM.RD) is a subject matter expert in MedTech Clinical Regulatory affairs, with over 20 years of experience in regulatory strategy, clinical validation, and market access. As the Clinical Regulatory Affairs Director at CLIN-r+, Jacqueline is the primary liaison for clinical evaluation and biocompatibility queries from auditors, specialising in closing out non-conformances and ensuring alignment with the latest ISO standards.



MARCEL DÖRKES

Eurofins Medical Device Consulting

Marcel has an academic degree (MSc) in molecular biology and an advanced toxicological expertise by further training. Marcel has been working in the field of evaluating the biological safety of medical devices since February 2018 and is now the Head of Medical Device Consulting in Germany. Marcel Dörkes' expertise includes the biological safety assessment of medical devices and related toxicological issues including strategy planning, chemical characterization procedures and overall biological risk assessments. Marcel is member of ISO TC 194 and involved in several working groups including ISO 10993-1, ISO 10993-17 and ISO 10993-18.

**TORBEN GEHRING****Eurofins Medical Device Testing**

Dr Torben Gehring is the head of the haemocompatibility and cytotoxicity group in the in vitro pharmacology and toxicology department at Eurofins Medical Device Testing in Munich. He completed his PhD at the Helmholtz Centre Munich, at the Institute of Molecular Toxicology and Pharmacology. He joined Eurofins Munich in 2020 as Head of Haemocompatibility Testing, taking over as Group Leader of Cytotoxicity in early 2022. He also took over as head of the haemocompatibility group in mid-2023 and has been responsible for both groups ever since.

**DR. HELGE GEHRKE****Eurofins Medical Device Testing**

Dr. Helge Gehrke is a Senior Scientific Director for in vitro Toxicology / Alternative Methods and a European Registered Toxicologist (ERT), holding a PhD in Nanotoxicology. He has been involved in the field of toxicology for more than 14 years and has a broad expertise in the areas of genetic toxicology, alternative methods, 3D cell culture models, cytotoxicity, hemocompatibility and nanotoxicology. As a toxicologist, he actively promotes the development the establishment of current alternative methods for the evaluation of biological safety within the Eurofins network but also in the context of international committees (NETVAL) and is an expert member of several working groups of ISO WG TC/194.

DR. MICHAELA HAJEK
3R LifeScience GmbH

Michaela is an experienced management and technology expert with focus on target-orientated development and approval activities for medical devices. She holds a PhD in Chemistry from Friedrich-Schiller University, Jena and an MBA from Cambridge University. For more than 20 years Michaela supports medical device companies by establishing and maintaining quality-relevant management processes throughout the entire product life cycle. Her activities include various interim management roles and operational support during MDD/MDR transition, for product approval, registrations and certification activities as well as the development of QM systems and risk-based processes for biological, technical and clinical product safety and post-market surveillance. Michaela is passionate about creating operational frameworks to allow an efficient certification and maintain medical devices throughout their product life.

LISA HEILEMANN
Eurofins Medical Device Sterile Packaging

Lisa completed a Master's degree in Biological Sciences in 2016. Since then, she has conducted validations of medical devices in accordance with ISO standards 19227, 11135, 11137 and 11607 for cleaning, sterilisation and packaging at Eurofins. Her core areas of focus include packaging and transport validation, ageing studies, gamma and EO sterilisation, regulatory processes, and quality management. As a long-term employee of the validation and quality assurance department, she has excellent qualifications. Since 2021, she has been one of two heads of validation. As of 2025, she has taken on the role of sole Head of Validation. Since 2022, Lisa Heilemann has been a member of the DIN standards committee for the packaging and sterilisation of medical devices, where she shares her expertise and skills with other experts.

**YANA KATSMAN****Eurofins Medical Device Consulting**

Yana Katsman holds a degree in Biomedical Engineering and has spent the past decade working in the medical devices industry. Currently, she serves as the Business Unit Lead for the Israel consulting group, specialising in active medical devices and software-based solutions.

With extensive experience in this field, Yana stays well-informed and up to date with the latest advancements, regulations, and guidelines, particularly in the areas of medical technology and cybersecurity. This allows her to navigate complex challenges and contribute to innovative, compliant solutions.

**BEAT KELLER****SMDC Swiss Medical Device Consulting GmbH**

Beat Keller is the Founder of SMDC Swiss Medical Device Consulting GmbH and a regulatory affairs expert with extensive experience in medical device compliance and international market access. He supports manufacturers in meeting European and Swiss regulatory requirements, with a particular focus on CE marking and conformity assessment procedures. Drawing on more than 15 years of practical experience and active involvement in standardisation work, he helps companies navigate regulatory complexity and bring devices to market efficiently and compliantly.

**DR. ING. JANIN LEUCKERT****3R LifeScience GmbH**

Janin is an experienced Project Manager with key expertise in connecting market needs and product development objectives with the overall quality and regulatory requirements management of medical devices.

She holds a PhD in mechanical engineering from TU Berlin and has worked in the industry for more than 10 years before joining 3R LifeScience, Berlin. She combines in-depth developing expertise with regulatory knowledge to set up projects in the best possible to efficiently manage different stakeholders for structured design input and output activities, product life cycle management and Post Market Surveillance activities. Janin is passionate about making R&D activities tangible and transparent and to allow creativity and focus under tougher regulations in the medtech industry.

**MARGHERITA MICCHELI****Eurofins Biolab Consulting**

Margherita Miccheli is a Senior Medical Device Consultant with over ten years of experience in Quality Assurance and more than eight years of experience in Regulatory Affairs. She holds a Master's degree in Genetics and Molecular Biology from Sapienza University of Rome.

Margherita has supported numerous companies, helping them increase their presence on EU market and non-EU markets driving revenue through faster market access and tailored regulatory strategy. She has been involved in implementing of different Quality Management System according to ISO 13485 and the certification of numerous medical devices based on substances, including sterile medical devices.

**JANA OSTERRITTER****Eurofins Medical Device Consulting**

As a biomedical engineer, Jana Osterritter has been involved in the development and approval of medical devices for several years.

At Eurofins Medical Device Consulting, she offers consulting services to clients in the field of quality management and technical documentation, but also regarding general regulatory issues relating to medical devices.

**JAN PEETERS****Peeters MD Consulting**

Jan Peeters has a background in chemistry. He has more than 30 years of experience in supporting medical device manufacturers regarding the safety evaluation of their products. He started his career at mdt medical device testing (later UL International Germany), where he held successively the following positions: Manager Physical-Chemical Laboratories, Director Testing Services and finally Scientific Director. He then moved to Eurofins Consulting Munich, where he served as Senior Consulting Specialist. Since July 2023, Jan is the founder of Peeters MD Consulting.

Jan specialises in biological and toxicological safety assessment of medical devices (ISO 10993, ISO 18562), packaging assessment, including shelf-life assumptions (ISO 11607) and reprocessing of reusable devices (ISO 17664). He is an active member of ISO/TC 194 Biocompatibility (various working groups).

**NAEL HAJ RACHID****Eurofins Medical Device Safety Testing**

Nael Haj Rachid is the Team Lead for Medical Devices at Eurofins Product Service GmbH in Reichenwalde, Germany. He has expertise in IEC 60601-1 and its collateral and particular standards. In his role, he manages regulatory compliance and safety evaluations across a broad range of medical devices, including high-frequency surgical equipment, nerve and muscle stimulators, electrocardiographic systems, medical beds, patient monitors, and other active medical devices.

Nael began his career as a Medical Device Test Engineer and has a proven track record in safety testing and quality assurance in accordance with ISO/IEC 17025. He holds an MSc in Biomedical Engineering from Hochschule Anhalt (with a thesis at TÜV SÜD) and a BSc in Medical Electronics Engineering from Aleppo University.

**DANIEL SEILER**
POC APP AG

Daniel Seiler is the co-founder and CTO of POC APP. He holds a mechanical engineering degree from the University of Applied Sciences and Arts Northwestern Switzerland (FHNW), complemented by a Master's in Mechatronics. Early in his career in 2002 as a development engineer, he ventured into the medical field, where he contributed to the development of various medical devices, including implants, surgical instruments, and medical therapy systems. Transitioning to a leadership role, he served as the Head of Innovation, steering interdisciplinary projects within the MedTech space and leveraging his expertise to offer extensive consulting services encompassing the entire process of bringing medical devices to market. Later, he took charge of the Medical Additive Manufacturing Group at the School of Life Sciences FHNW. Here, he delved into comprehensive research on medical metal, polymer, and ceramic 3D printing for the production of medical devices. In addition to his professional responsibilities, Daniel shares his insights as a lecturer for the Bachelor's and Master's Biomedical Engineering programs at FHNW and the University of Basel. As the CTO of POC APP, he successfully turns research and new technologies into practical applications for 3D print labs in hospitals.

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General Terms and Conditions

In the event of cancellation before January 24, 2026 50% of the fee will be refunded. Cancellations received after this date will not be refunded.

Eurofins Medical Device Services reserves the right to cancel or change the programme, speakers, date or Venue. If the event has to be cancelled, registrants will be notified as soon as possible and will receive a full refund of fees paid. Eurofins Medical Device Services is not responsible for airfare, hotel or other expenses incurred by participants.

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ONE STOP-SHOP SOLUTION FOR YOUR MEDICAL DEVICE NEEDS

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