Agenda
The “NEW CE” marking for IVD medical devices
-Important Changes-
– one day Workshop –

With special Guest from TÜV Rheinland – Mr. Ronald Sills

DATE 04th AUGUST 2017, Friday
TIME 9AM – 5PM
Registration starts at 08:30 AM
Lunch and tea break will be provided
VENUE San Diego Training and Conference Center, 350 Tenth Ave #950, San Diego, CA 92101, USA [VIEW MAP]

WORKSHOP ABSTRACT Goal: The workshop provides an overview of the NEW CE marking with a special focus on in-vitro diagnostics. It goes into details on specific critical subjects for the manufacturer and its Authorized Representative and outlines the changes a manufacturer must consider. The notified body TÜV provides its take on the detailed requirements for the technical documentation as well as performance evaluation and post-market performance follow-up.

The concepts are set and manufacturers who do not want to risk the CE marking for their products must evaluate the changes and additions NOW in order to prepare for a timely implementation. There will be a transition period but Europe does not allow “Grandfathering”.

It is important to know the new specific requirements for your products and the timelines available to make sure that your products and your company are ready for the “NEW CE” marking.
**Objective:** Understand the particular aspects the manufacturer must address today for the “NEW CE marking”.
Recognize the impact of the new legal concepts for the Importer and Distributors in relation with the manufacturer and also be prepared for the enhanced market surveillance by the authorities.
Be prepared for the new risk-based classification system for IVDs and the different conformity assessment procedures.

Know the notified bodies take on the examination of performance evaluations.

**Attendees:** Regulatory, compliance and product specialists should attend since it is imperative to fully understand the requirements to enable them in analyzing the impact for the product compliance and ultimately the impact on the company. Business owners and executive management should attend to understand the extent of the impact to apply the necessary resources in the right area of their company ensuring the compliance in continuing to market their products in Europe with the New CE marking.

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<th>08:30 – 09:00</th>
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| 09:00 – 10:30 | **The new regulatory system – Objective of the New Legislative Approach:**  
The member states must apply the new Regulations directly without transposing them into their national law.  
The overview sets the stage for the workshop. The issues that lead to the new regulation are outlined and the purpose of the regulation will be briefly discussed.  
Economic Operators (Manufacturer, Authorized Representative, Importer and Distributors) Scope and definitions – **What is Important to those Exporting to the EU?**  
(Chapter 1, 2)  
The manufacturer must know the responsibilities of the market chain in order to protect his products. The definitions for IVD medical devices and their accessories have been extended.  
Timeline for implementation, New legal aspects, Other aspects  
(Chapter II, VIII)  
The urgency of the implementation is given. It is important to know how long you may place products on the market with the current CE marking due to the very short transition period.  
Certain new legal aspects are being introduced and what the manufacturer needs to know to avoid any traps. |

| 10:30 – 11:00 | Coffee Break – Exchange of viewpoints among the participants |
| 11:00 – 12:30 | **New Classification and Conformity Assessment Procedures for IVDs:**  
Estimations were made that under the new IVDR up to 85% of IVD manufacturers will come into contact with Notified Bodies for the first time. New risk-based classification rules |
What do you have to consider and how to select the right Conformity Assessment Procedures for your products?

12:30 – 13:30
Lunch – Networking opportunity among participants

13:30 – 15:00
TÜV talks on Technical Documentation, Performance Evaluation and Post Market Performance Follow-up under the new IVDR

15:00 – 15:30
Coffee Break – Exchange of viewpoints among the participants

15:30 – 17:00

Proactive monitoring of your devices in the market shall be conducted. Trend reporting requirements are imposed based on post-market data. More stringent requirements for vigilance reporting are imposed on the manufacturer. Clear instructions are given to the EU Member States for their market surveillance.

ABOUT THE SPEAKER

MR. LUDGER MOELLER
President of Medical Device Safety Service GmbH (MDSS)
Chairman of MDSS Consulting and ITN Holding GmbH
Member of the European Commission Medical Device Expert Group (MDEG)
Member of the MDEG VIGILANCE Expert Group (MDEG Vigilance)
Vice-Chairman of the European Association of Authorized Representatives (EAAR) of the Ethics Committee of the Medical Council (Aerztekammer) for Lower Saxony

Previously, Lead Auditor with the Notified Body TÜV Rheinland

MR. PHILIPP HOHENBRINK
Consultant at Medical Device Safety Service GmbH (MDSS) since 2015. Dr. Philipp Hohenbrink is an IVD expert at MDSS focusing on the review of technical documentation prior to device notification with the Competent Authority. He is also safety officer handling vigilance cases for medical devices (especially IVD medical devices). He acquired his doctor's degree in the fields of evolutionary biology and molecular genetics.

Dr. Philipp Hohenbrink
Consultant at Medical Device Safety Service GmbH (MDSS) since 2015. Dr. Philipp Hohenbrink is an IVD expert at MDSS focusing on the review of technical documentation prior to device notification with the Competent Authority. He is also safety officer handling vigilance cases for medical devices (especially IVD medical devices). He acquired his doctor's degree in the fields of evolutionary biology and molecular genetics.
MR. RONALD SILLS

Lead Auditor, Medical – TÜV Rheinland of North America

Authorizations for:
ISO 13485:2003 under CMDCAS
MDD 93/42/EEC
MDSAP

Expertise in:
Microbiology
Sterilization technologies, validations and qualifications
Clean rooms and hygiene requirements
Biocompatibility requirements
Clinical evaluation reports

ABOUT MEDICAL DEVICE SAFETY SERVICE (MDSS)

MDSS specializes in European Regulatory Affairs and is headquartered in Germany.

MDSS pioneered the European Representation and is well known and respected with the Competent Authorities in EU and serves both the Medical Device and the In Vitro Medical Diagnostic industry.

ABOUT TÜV RHEINLAND

TÜV Rheinland is accredited by OSHA as an NRTL and offers product safety testing and regulatory solutions for medical devices, including regulatory solutions for determining compliance to IEC 60601 and ISO 14971. TÜV Rheinland also provides certification services to EN ISO 13485, MDD, IVD, AIMD and ISO 13485 under CMDCAS. Additional services include RoHS/REACH, EMC/wireless/radio, cybersecurity and Market Access.

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