



# Breakfast seminar

## MDR and its potential impact on Technical Files

QAdvis – Seminar, Sthlm/Uppsala/Lund, March 2017



## QAdvis key competence areas

### QMS in-the cloud

Turn key QMS  
Digital signatures  
Efficient and lean  
Validated and compliant

### System development

Project management  
Product software validation  
Regulated software validation  
Requirement management  
Risk management  
Verification and validation  
Process validation

### QA&RA/Clinical Consulting

Interim management  
Expert advise  
Audits/Mock audits/Due diligence  
Warning letters, compliance projects  
PMA, 510k, CE-mark  
Global regulatory support  
Vigilance, recall, post market surveillance  
Clinical evaluation and clinical studies

### Training/courses

CE-marking  
ISO 13485 & 21CFR820  
IEC 62304 & IEC 82304-1  
IEC 60601-1  
IEC 62366-1  
SW life cycle  
SW risk management  
Risk management  
And more...

### Lean and Six Sigma

Training and Consulting  
In cooperation with USA  
based partner.

### European Authorized Representation

Providing European representation  
for non-EU MedTech companies  
Active board member of EAAR: European  
Association of Authorised Representatives

## Presentation of the speaker Anneli Wiedenkeller



- Worked within the medical device industry since 1988 (manufacturing, QA, R&D, RA).
- Background mainly from electrotechnical devices.
- Working the recent years as a senior product assessor (active and non-active devices) at a Swedish MDD NB.

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# Agenda



- Transition of MDD, AIMDD and IVDD to MDR and IVDR
- Major changes in recent years
- Technical Files (MDR/IVDR annex II and III)



Transisiton of MDD Essential Requirements to General safety and performance requirements (GSPR)

# Change from AIMD, MDD and IVDM to....

## Directives



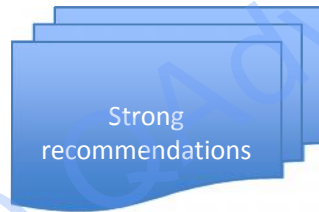
AIMDD (now: amendment 4)



MDD (now: amendment 5)



IVDMD (now: amendment 3)



- Guidance MEDDEV:s
- Consensus statements
- Informative documents
- Harmonized standards

## Regulation



MDR



IVDR

## Probable timelines

European Council vote on latest proposal 7 March 2017

European Parliament vote 20 March 2017

**Expected to be formally published in late May or early June 2017**



## Transition period

- MDR will become applicable in three years after acceptance (2020)
- IVDR will become applicable in five years after acceptance (2022)





# Translation to Swedish

**LÄKEMEDELSVERKET**  
MEDICAL PRODUCTS AGENCY

Lättläst  
Webbkarta  
Kontakta oss  
English

Läkemedelsfakta  
Sök läkemedel eller substans  
Utökad sökning | A-Ö

Webbplats  
Sök hela webbplatsen

Hem / Företag / Medicinteknik / Frågor och svar /

## Frågor och svar - nya förordningar för medicinteknik

**NYTT!** Vilken nomenklatur ska användas vid registrering av medicintekniska produkter i EUDAMED?

En gemensam, internationellt vedertagen, nomenklatur ska användas vid registrering av produkter i EUDAMED. EU-kommissionen säkerställa att denna nomenklatur ska tillhandahållas kostnadsfritt för tillverkare och andra fysiska eller juridiska personer som är skyldiga att använda nomenklaturen vid tillämpning av förordningen.

**NYTT!** Hur får man marknadsföra medicintekniska produkter?

Förordningen har en artikel om marknadsföring där det framgår att det är förbjudet att i märkning, bruksanvisning och marknadsföring vilseleda användaren eller patienten gällande produktens avsedda ändamål, säkerhet och prestanda genom att tillskriva produkten egenskaper den inte har, ge en oriktig föreställning avseende behandling eller diagnos, funktioner eller egenskaper som produkten inte har, underlåta att informera om en sannolik risk vid användning av produkten eller föreslå andra användningsområden för produkten än de som angavs som avsett ändamål i samband med bedömning av överensstämmelse.

**Relaterad information**

- ➔ **Förslag förordning medicintekniska produkter** → Utg: 9 Augusti 2016 (15 juni 2016)
- ➔ **Förslag förordning medicintekniska produkter för in vitro-diagnostik** → Utg: 31 Augusti 2016 (15 juni 2016)
- ➔ **Proposal MDR** → Ed: August 9, 2016 (15 June 2016)
- ➔ **Proposal IVDR** → Ed: August 31, 2016 ("This is a "clean" version without any difference between "new text" and text from the Commission proposal.")

**HÄLSO- & SJUKVÅRD**

**APOTEK & HANDEL**

**ALLMÄNLIET**

**FÖRETAG**

- Homeopatiska läkemedel
- Kosmetika
- Lagerberedningar
- Läkemedel

**Medicinteknik**

- Introduktion till regelverket
- Regelverket
- Publicerade ändringar av Läkemedelsverkets föreskrifter
- Vägen till CE-märket
- Kvalificering och klassificering
- Kliniska prövningar
- Olyckor och tillbud
- Registrering
- Konsultation, läkemedelssubstans
- Exportintyg
- Referensdokument, rapporter och vägledningar - medicintekniska produkter

## Final draft (?)

"Position of the Council at first reading..", dated 22 Feb 2017:

- BSI website

[https://www.bsigroup.com/en-GB/blog/BSI-Medical-Device-Blog---The-next-step-to-MDR-adoption/?utm\\_source=pardot&utm\\_campaign=SM-SUB-LG-CN-Blog1-ALL-1702A&utm\\_medium=email&utm\\_content=CTA](https://www.bsigroup.com/en-GB/blog/BSI-Medical-Device-Blog---The-next-step-to-MDR-adoption/?utm_source=pardot&utm_campaign=SM-SUB-LG-CN-Blog1-ALL-1702A&utm_medium=email&utm_content=CTA)

- TÜV Rheinland website

[http://www.tuv.com/en/corporate/business\\_customers/product\\_testing\\_3/medical\\_devices\\_engineering\\_1/medical\\_products.html](http://www.tuv.com/en/corporate/business_customers/product_testing_3/medical_devices_engineering_1/medical_products.html)

## Globalization



- EU MDR/IVDR (Q2 2017?)
- MEDDEV 2.7.1 rev 4 (June 2016) ("CLINICAL EVALUATION...")
- QMS: ISO 13485:2016
- HA Analysis: EN ISO 14971:2012 annex Z and NBMED consensus paper  
[http://www.team-nb.org/wp-content/uploads/2015/05/documents2014/NBRG\\_WG%20RM\\_Interim\\_NBmed\\_Consensus\\_Version\\_140812\\_1\\_1.pdf](http://www.team-nb.org/wp-content/uploads/2015/05/documents2014/NBRG_WG%20RM_Interim_NBmed_Consensus_Version_140812_1_1.pdf)

## All "old" news still not clear

- European database on medical devices (Eudamed)
- Unique Device Identification (UDI)
- Common specifications
- Reprocessing of single use devices
- Changed of risk classes (IVDD classes List A and B/IVDR classes A, B, C and D)
- Person responsible for regulatory compliance
- Responsibility of European Representative etc
- .....

## Structure of MDR and IVDR

- Article 2 Definitions
- Article 10 General obligations of manufacturers
- Article 15 Person responsible for regulatory compliance

## MDR Annexes (tot 17, 15 in IVDR)

**I General safety and performance requirements**

**II Technical documentation**

**III Technical documentation on post-market surveillance**

IV EU Declaration of conformity

V CE marking of conformity

VI Information to be submitted upon the registration of devices and economic operators in accordance with Articles 29(4) and 31; core data elements to be provided to the UDI database together with the UDI-DI in accordance with Articles 28 and 29; and the UDI system

VII Requirements to be met by notified bodies

**VIII Classification rules**

IX Conformity assessment based on a quality management system and assessment of the technical documentation



## MDR Annex (tot 17)

X Conformity assessment based on type examination

XI Conformity assessment based on product conformity verification

XII Certificates issued by a notified body

XIII Procedure for custom-made devices

**XIV Clinical evaluation and post-market clinical follow-up**

**XV Clinical investigations**

XVI List of groups of products without an intended medical purpose referred to in Article 1(2)

XVII Correlation table

## Technical Documentation

- About 10 "hits" in MDD and 4 in IVDD
- About 100 "hits" in MDR and IVDR
- Own sections/annex

## Example: Product/TF "Big five" of MDD contra MDR

| MDD                                   | MDR  |
|---------------------------------------|--|
| Intended Purpose/Use                  | Intended Purpose/Use   |
| Risk classification, annex IX         | Risk classification, annex VIII  |
| Essential Requirements (E R), annex I | General Safety and Performance Requirements (GSPR), annex I  |
| Clinical evaluation, annex X          | Clinical evaluation XIV Clinical evaluation and post-market clinical follow-up<br>XV Clinical investigations |
| EC DoC, annex VII                     | EC DoC, annex IV   |

Increased dependence

TF



QMS

## Importance of root cause analysis has increased in TF

GHTF/SG3/N18:2010

Quality management system –Medical Devices –  
Guidance on corrective action and preventive action and related QMS processes, extract:

### 6.2 Identify Root Cause

Causes or contributing factors of detected nonconformity or potential nonconformity should promptly be identified so that corrective action can be taken to prevent recurrence, or preventive action taken to prevent occurrence.....



Update of a/several processes?  
Need of a process?  
Not following existing processes?

## MDR/IVDR Annex regarding TF

**I General safety and performance requirements**

**II Technical documentation**

**III Technical documentation on post-market surveillance**



## STED (“non-binding guidance”)

Summary Technical Documentation for Demonstrating Conformity to the Essential Principles of Safety and Performance of Medical Devices (STED)

<http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n011-2008-principles-safety-performance-medical-devices-080221.pdf>

Summary Technical Documentation (STED) for Demonstrating Conformity to the Essential Principles of Safety and Performance of In Vitro Diagnostic Medical Devices <http://www.imdrf.org/docs/ghtf/final/sg1/technical-docs/ghtf-sg1-n063-2011-summary-technical-documentation-ivd-safety-conformity-110317.pdf>

## Requirement of structure in TF

..”thereof to be drawn up by the manufacturer shall be presented in a clear, organised, readily searchable and unambiguous manner.”

## MDR Annex II subsections

### 1. DEVICE DESCRIPTION AND SPECIFICATION, INCLUDING VARIANTS AND ACCESSORIES

1.1. Device description and specification

1.2. Reference to previous and similar generations of the device

## MDR Annex II subsections

### 2. INFORMATION TO BE SUPPLIED BY THE MANUFACTURER

## MDR Annex II subsections

### 3. DESIGN AND MANUFACTURING INFORMATION

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## MDR Annex II subsections

### 4. GENERAL SAFETY AND PERFORMANCE REQUIREMENTS



## MDR Annex II subsections

### 5. BENEFIT-RISK ANALYSIS AND RISK MANAGEMENT

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## MDR Annex II subsections

### 6. PRODUCT VERIFICATION AND VALIDATION

#### 6.1. Pre-clinical and clinical data

#### 6.2. Additional information required in specific cases

## MDR Annex II subsections

### ANNEX III

### TECHNICAL DOCUMENTATION ON POST-MARKET SURVEILLANCE

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## Summary of areas in focus

- Risk Management
- Post Market Surveillance
- Clinical data

## Summary

- Start to read!
- Gapanalysis!



Thank you for your attention!  
Questions & Answers





## QAdvis can support you as needed



Contact:

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### CE marking support:

- Technical File creation
- Pre-assessment of Technical Files
- EN ISO 13485:2016 (QMS)
- EN ISO 14971 (Risk management)
- EN 62304 (Software)
- EN 62366-1 (Usability)
- Support regarding clinical data e.g. clinical evaluation report