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MDR, RELEVANT CHANGES AND QUESTIONS – WHAT ONE SHOULD CONSIDER

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Agenda

The big RA-Picture
10 most significant changes with MDR
RA-Strategy, relevant changes
Some important points to consider
There are as well Chances
ISS at a glance
Take-home message

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The big RA-Picture

easier

- 1003 device types exempt from 510(k) in 2017
- D. Trump: De-regulation
- MDSAP
- Digital submission tools
- e-Submissions

more complex

- MDR
- ISO 13485:2016
- cyber security, Interoperability
- new challenges (RU, CN, India)
- OEM/PLM increasingly difficult (MDR)

Some hypotheses

- MDR complicates life for companies, a chaotic phase lies ahead (until around 2020)
- Clinical topics gain more attention and are becoming a major obstacle
- Some Notified Bodies are not going to tackle the obstacle the MDR poses
- V&V, CSV (GAMP), qualification is going to become an important issue due to the new version of the ISO 13485
- Increased (price) transparency (UDI etc.) fuels price pressure

- Small and middle-sized companies are going to struggle to stomach the MDR -> Mergers as well as new forms of cooperation gain importance
- USA reduces regulatory requirements, in contrast they are increased in the EU
- Digitalization becomes a major topic in the med-tech/health industry
- Big companies are not able to easily “shop” for innovations from small ventures anymore

However

- The regulations and obstacles are the same for everyone
- RA-strategies are partly responsible for the success

This is exactly where the opportunities for modified RA-strategies lie

Whoever improves organization in RA & Clinicals has a benefit over others

10 most significant changes with MDR

1. More clinical data needed (pre- and post market)
2. Additional hurdles for high risk products (scrutiny process)
3. Increased requirements regarding tracebility (inclusive suppliers)
4. Introduction of UDI (Unique Device Identifier)
5. Regular update and publishing (Eudamed) of clinical and safety reports
6. A “person responsible for Regulatory Compliance” has to be installed
7. Re-classification of some products
8. Higher responsibility and transparency regarding sales volume, suppliers, distributors etc. of a product (Eudamed)
9. Some “non medical products” come under the umbrella of the MDR
10. OEM/PLM is becoming almost impossible in some constellations

RA-Strategy, relevant changes

Up until now	Future
Pricing per Market	**High Transparency** through UDI and Portals -> Strategy has to be global from the outset
Avoid **Clinicals** if possible	**Plan Clinicals from the outset**, PMCF becomes the normal case
Fight the competitor	**Fight & Partnership**. Equivalence of the CER demands profound insight into the TechFiles

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Up until now	Future
Choose the **best fitting Notified Body**	NBs are getting rare and a **bottle neck**. We still do not know which NB will make it for the MDR
The **collegial** and understanding auditor we know for many years	NB has to be strongly hedged, becomes **stricter**, will have to enforce additional requirements, Auditors will change frequently
Do it yourself RA	Partial or complete **outsourcing** will increasingly become an issue (Know-how, cost-efficiency, independence from individual persons)

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Up until now	Future
Step by step internationalization	Expansion as broad as possible in many markets **simultaneously**
Distributor does what he wants the way he wishes to	Distributor is connected **more closely** to the processes of the manufacturer (Traceability, Vigilance, Eudamed etc.)
UDI (USA) has been reached	**Additional markets** are going to adopt the UDI relatively quickly, labeling and UDI-DB-Management become more demanding -> Tooling, Interfaces, ERP

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Up until now	Future
RA and Sales & Marketing work comparatively **independent** of one another	RA, Clinicals and Sales & Marketing are **closely connected**
Product phase-out barely exists	Under MDR **all products** have to be **newly registered**. This leads to many forced phase-outs -> Include phase outs and "final-certifications", in connection with MDR, in the planning.
Keep RA as **lean** as possible	"Person responsible for Regulatory Compliance" and other additional requirements drive costs. -> RA is getting **more expensive**

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Some important points to consider

- MDR is not finished yet. In Implementing Acts (**IA**) and Delegated Acts (**DA**) we expect clarifications but as well surprises
- **UDI** (Unique Device Identification) will be introduced in some CE countries prior to the MDR (e.g. Netherland only accepts Implants with UDI from July 2018 onwards)

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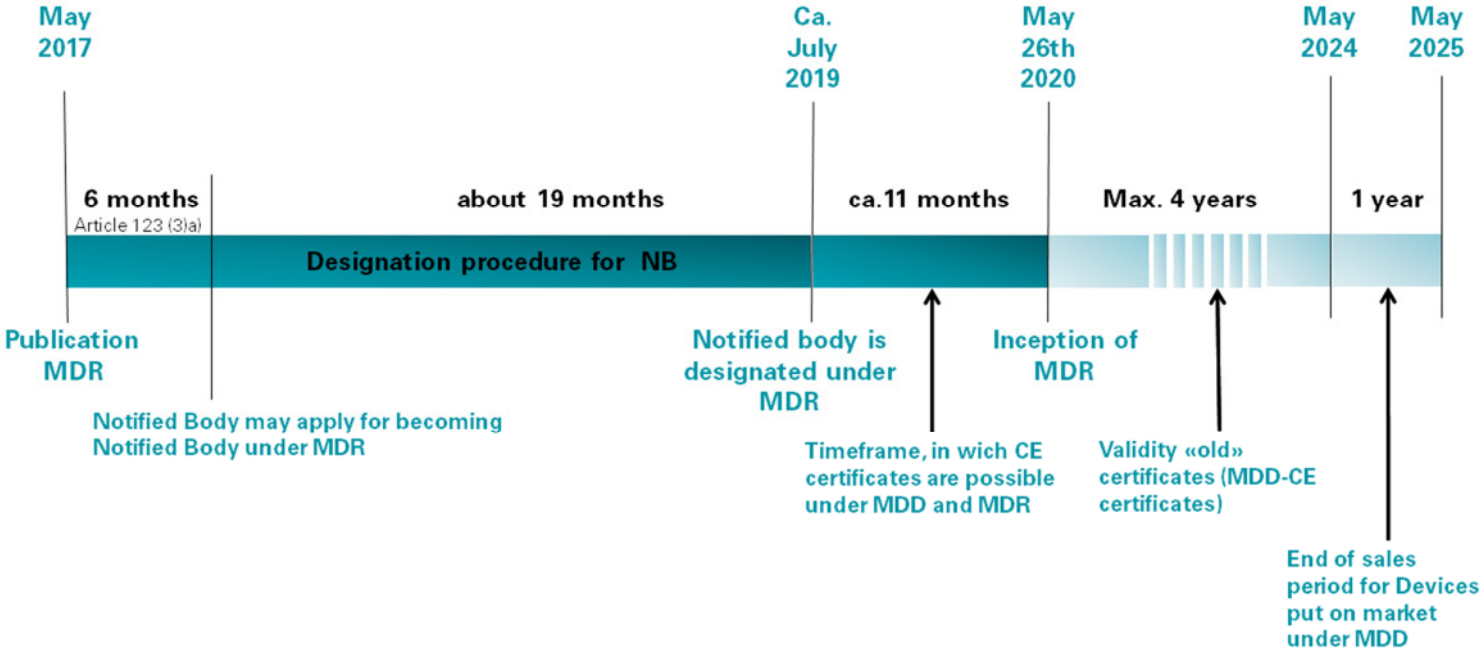
Timeline MDR



Timeline-Impact I: Phase outs of “non-transferred” MDs

Trigger

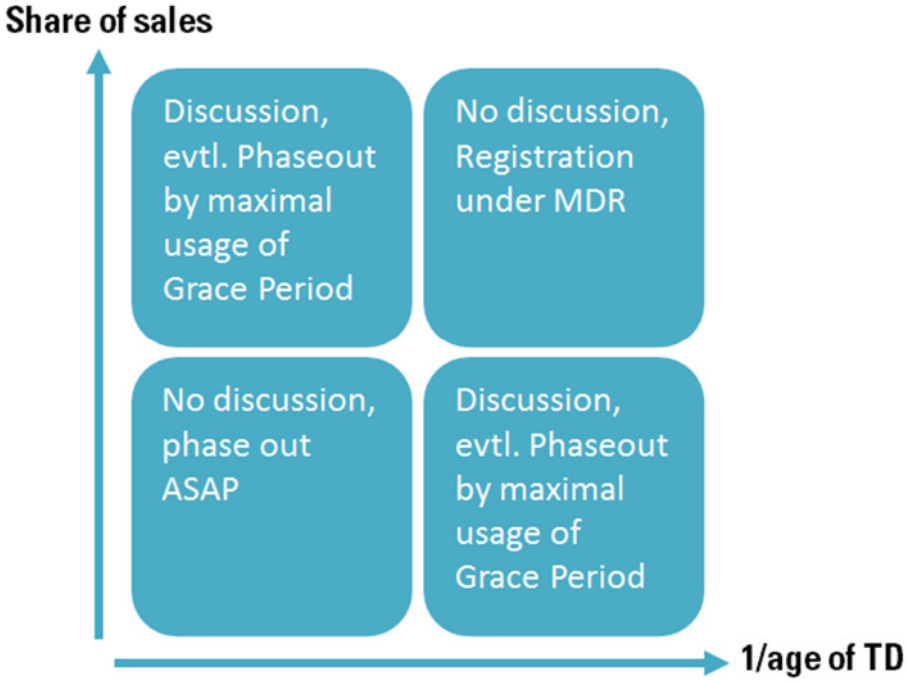
No-Grandfathering -> means: each product has go through a full blown registration process under MDR

Means:

- Too expensive for many products (manly low-volume products)
- Therefor many products will be phased-out
- In many companies, procedures, tools etc. are not in place for phase-outs

There is the danger of a critical shortage for specific Medical Devices for some patient groups -> Politics to find workarounds

Phase out: a simple decision clustering which can help



Timeline-Impact II: MDD Class I products which are up-classified under MDR

Examples

- **Software** driven MD/ Medical Apps, KIS-Systems, etc. which were Class I under MDD:
- **substance based medical devices** (e.g. nose sprays, cooling creams…) are up classified in many cases
- **Non-medical devices covered by the MDR** (e.g. contact lenses, liposuction, tattoo removal etc.)

Those products need a certification in 2020.

Means

- In most cases: ISO 13485 has to be built up and certified (if not available yet)
- A Notified Body has to do the conformity assessment
- Or you find another solution (like Decomplix, effectum)

OEM/PLM: new approaches needed

Actual situation:

So far, most NB accepted the ZLG document which allowed “fast tracks” for PLM/OBL (ZLG 3.9 B16)

At the latest, with the MDR, classical “OEM” will not be possible as it was before.

However, a letter which was sent out by the Swiss NB SQS from May 16th 2017 says:

> Die SQS wird bei der EG-Konformitätsbewertung von Medizinprodukten der OBL Hersteller ab sofort das vollständige EG-Konformitätsbewertungsverfahren gemäss RL 93/42/EWG durchführen. Alle „OEM/OBL“ Hersteller von Medizinprodukten werden damit verpflichtet der SQS die komplette Technische Dokumentation zur Prüfung bereit zu stellen.

Trigger

Rules which require access to the whole technical file. OEM suppliers are normally not willing to provide those.

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Impact

- Highly strategic relevance for all OEM products in your company
- Starts right now (as with SQS) or in the near future
- Can have huge impact on your portfolio

Options

- Clarify with your NB
- Find a solution with the OEM
- Reduce the portfolio
- New solution (other provider, Decomplix, distributor-model)

UDI and Eudamed

- Eudamed will play an important role as THE database in the EU MD regulation world
- Feeding Eudamed cause some work but will not be the major challenge of the MDR
- Eudamed will involve additional players, like your distributors
- Eudamed will create more visibility of your company and your products
- UDI will be implemented very similar as in the US (same coding systems, mainly GS1 & HIBC)
- Centralized UDI Database (GUDID @ FDA) will be in Eudamed

No problem then?

Impact UDI and Eudamed I

- You will have to manage information about the same product/company provided by different players in different databases
- Labeling will become more and more a challenge. Why not realign the labeling process?

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There are as well Chances

- Original sound of a CEO: „*finally we are forced to clean up our portfolio*“
- UDI is an invitation to digitize the Labeling-Process
- Prozesse zu überdenken, da verschiedene Prozesse eh angepasst werden müssen
- Partnerships are becoming more important, this normally is a step forward
- Big players are becoming even slower by the MDR. This contains chances for SMEs

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ISS at a glance

- Fully dedicated to MedTech
- 35 high profile employees (Engineers, Scientists, Medical Doctors)
- Projects, services and products for MedTech companies in the fields of Regulatories, Clinicals, Software development and QMS
- Certified per ISO 13485, IEC 62304 etc., audited CRO services (BVMA)
- International customers in various subfields of the MedTech industry
- Dedicated to "Doing" rather than "Consulting only"
- Founded in 2003 as spin-off from Ziemer Group, an established manufacturer of ophthalmic High Tech devices
- Co-founder of the joint venture Decomplix AG
- Located in Biel, a core area of Switzerland's watchmaking and high-tech industry

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How we can help out with MDR topics

- Company specific **MDR Gap Analysis**
- **Update** Techfiles to MDR
- Adopt processes, introduce **new processes** (eg. PMS, Phase out, Vigilance, PSUR, SW-Development…)
- Create **templates** for PMS, CER, PSUR etc.
- **PMCF/CRO** activities for PMCF or pre market clinical studies
- Updating **Clinical Evaluations** to Rev. 4
- Introduction of **UDI** or updating existing processes for UDI
- Prepare a multithread parallel **re-certification** under MDR with the means of REGULA™
- Provide shared services for the "**Person responsible for Regulatory compliant**"
- Provide shared ISO 13485 **QMS and Legal manufacturing** with the means of Decomplix

Check out some of the customer feedbacks

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ISS Services

	Prestudy	Project Implementation	Market Introduction
BD Down to earth	Business Modell Dev.		Project Coaching
Q & Eng. Power by	ISO 13485/FDA 21CFR 820	Tech File, Audit Support, V&V	CAPA, Complaint handling
RA Services Global Markets	RA Strategy	Global Registrations	PMS, Re-Registrations
Clinical Srv. CRO for MedTech	Cl. Strategy	Study Planning, Approvals, Operations, Clin. Eval., Medical Writing, PMCF	
Software Dev. & Val.	Req. Engineering	SW-Development, SW Validation	Product Support

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ISS Products

	Idea	Implementation	Market Introduction	Maintenance
BD Down-to-earth	BD Workshops			
Q & Eng. Avoid problems	UDI Impact analysis			
RA Services Global Markets	MDR Impact analysis		RA-Intelligence	REGULA™
Clinical Srv. CRO for MedTech				
Software Applied IEC 62304	RFID Consumable Management		Medical Grade Bootloader	

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Take-home message

- Make it a **top management** topic
- Start the MDR activities from both ends, **gap analysis** and from a **strategic level**
- Consider **RA & Clinical-Strategy** as a unity that needs to be taken very seriously
- Gather now as much clinical data of existing products as possible (PMCF)
- Mind the budget, RA & Clinicals will be more expensive in the future
- Include **phase-outs** in the portfolio-planning
- Look for **partnerships**
- Try to use the necessary changes for **sustainable improvements**
- **Tools** like Regula™ **alternatives** like Decomplix might help