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Effects of the European MDR on the Quality Management System

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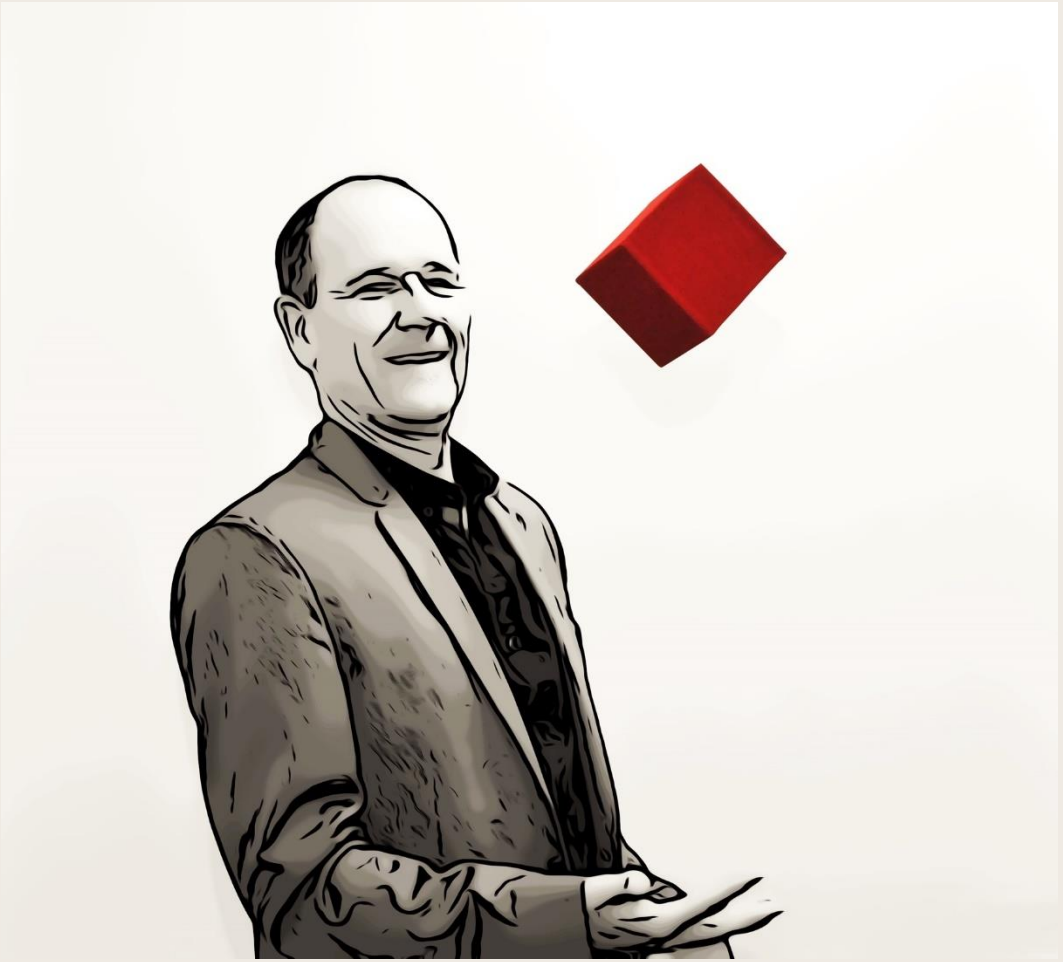
In 2014 Karl-Heinz moved to Switzerland to SIAS AG, a company developing and manufacturing automatic liquid handling robots (IVD).
In June 2017 he joined confinis, supporting Medical Device and IVD manufacturer in tackling their challenges around Quality Management.
Furthermore he is a certified auditor DGQ/EOQ.



MDR: Effects on QM-System (Articles)

Article	Requirement/Change	Action	Process/SOP
I, A1	Subject Matter and Scope	Check the application	Q-Manual
I, A2	Definitions (71!) More details will be provided in one of the following blog-posts in this series.	Check and adjust your definitions → separate document as annex to Q-Manual (sub-process)	Q-Manual as Annex or all SOP's
II, A5	Placing on the market, putting into service	Check if applicable and how your QMS describes these requirements	Development, Registration, Installation
II, A6	Distance Sales	Check your sales- and registration-processes acc. to this article	Sales, etc.
II, A7	Claims	See Annex I, Chapter 3	Labeling
II, A8	Use of Harmonised Standards	Check your list of standards, also relevant for EO's	Development
II, A9	Common Specifications	Adapt the CS in your system when available	QMS

MDR: Effects on QM-System (Articles)

Article	Requirement/Change	Action	Process/SOP
II, A10	General Obligations of Manufacturers	Check your QMS acc. to this article: do my processes fulfil all requirements?	QMS
II, A11	Authorised Representative	Update contracts, tasks, documentation → TD	
II, A12	Change of Authorised Representative	Ensure Feedback: Complaints and Reports	PMS
II, A13, 14, 16	General Obligations of Importers, Distributors	Update/adapt (QAA): Registration, Labeling, Storage, Transport, Complaint-Handling, Feedback, PMS	several
II, A15	Person responsible for regulatory compliance	Create a job describtion, adapt this function in your organisation chart	HR

MDR: Effects on QM-System (Articles)

Article	Requirement/Change	Action	Process/SOP
II, A17	Single-use and reprocessing	Adapt/implement the required processes incl. traceability and labeling Note: national provisions!	Several
II, A18	Implant Card and Information	Provide card and information: Actual, website, languages, ...	Labeling
II, A19	EU Declaration of Conformity More details will be provided in one of the following blog-posts in this series.	See Annex IV	Develop., Registration
II, A20	CE-Marking of Conformity	See Annex V	Labeling
II, A21	Devices for Special Purpose	See Annex XIII and XV	Labeling
II, A22	Systems and Procedure Packs	«development» of systems: validation, packaging, labeling Possibly own DoC	Development

MDR: Effects on QM-System (Articles)

Article	Requirement/Change	Action	Process/SOP
II, A23	Parts and Components	Clear declaration of spare-parts ⇒ Spare-part list in IFU Change of performance: independent device (!)	Development, Service, Labeling
III, A25	Identification within Supply Chain	«appropriate level of traceability» → Who was involved?	Traceability
II, A26, 27, 28, 29	«UDI»	Adapt the relevant processes to these requirements See Annex VI More details will be provided in one of the following blog-posts in this series.	Development, Labeling
III, A31	Registration of Manufactures, etc.	If running: register your Company and add the SRN in your QM More details will be provided in one of the following blog-posts in this series.	QM

MDR: Effects on QM-System (Articles)

Article	Requirement/Change	Action	Process/SOP
III, A32	Summary of safety and clinical performance	Only valid for class III and implants. - Create template acc. (2) - Determine the languages needed (user, patient) - Establish process to send it to your NB → validation	Clinical Evaluation
III, A33-34	EUDAMED	Wait until EUDAMED is available	
IV	Notified Bodies More details will be provided in one of the following blog-posts in this series.	Make sure that your NB keeps his authorization	
V, A51	Classification More details will be provided in one of the following blog-posts in this series.	Classification changed! → new assessment necessary, see Annex VIII	Development
V, A52-60	Conformity Assessment Procedures More details will be provided in one of the following blog-posts in this series.	Adapt your process to the new requirements depending on your products; see Annex IX to XI	Development

MDR: Effects on QM-System (Articles)

Article	Requirement/Change	Action	Process/SOP
VI, A61-82	Clinical evaluation and Clinical investigations More details will be provided in one of the following blog-posts in this series.	Implement the new requirements: e.g. PMCF plan as a process? see Annex XIV to XV	Clinical Evaluation, PMS, etc.
VII, A83	PMS-System of the manufacturer More details will be provided in one of the following blog-posts in this series.	Check your PMS-process to deliver the results defined in (3) and to show the interaction between CAPA and Vigilance (4)	PMS, 13485, 8.4 Data Analysis
VII, A84	PMS Plan	The process shall represent the plan (see Annex III, 1.1) incl. statistics, observation period (see A88)	PMS (RM)
VII, A85	PMS Report **Class I**	Template to document the results of A84 → «update when necessary»	PMS (RM) TD

MDR: Effects on QM-System (Articles)

Article	Requirement/Change	Action	Process/SOP
VII, A86	Periodic Safety Update Report (PSUR) **Class IIa, IIb, III**	Template to document the results of A84: Class IIa → at least every two years Class IIb+III → annually Class III + Implants: PSUR to NB per EuDaMed Other: «make available to NB»	PMS (RM) TD
VII, A87	Reporting of serious Incidents and Field Safety Corrective Actions	Adapt the process: serious incident: ≤ 15 days death or an unanticipated serious deterioration: ≤ 10 days serious public health threat: - Immediately, not later than 2 days → Reporting in EuDaMed	Complaint, CAPA, Vigilance

MDR: Effects on QM-System (Articles)

Article	Requirement/Change	Action	Process/SOP
VII, A88	Trend Reporting	Add these in the PMS-process, define methodology for statistics and observation period	PMS, RM, Data Analysis
VII, A89	Analysis of serious incidents and FSCA	Analysis → CAPA CAPA-Team includes CA (1) Actions → et al FSCA Report → EuDaMed	CAPA, FSCA
VII, A90	Analysis of Vigilance Data	One trigger of CAPA	CAPA
VII, A91	Implementing Acts	Possible Trigger for other/more requirements	PMS, Data Analysis, CAPA
VII, A92	Electronic system on vigilance and on PMS	Add submission of report to the processes will generate queries!	several

MDR: Effects on QM-System (Articles)

Article	Requirement/Change	Action	Process/SOP
VII, A93-100	Market Surveillance	Input to PMS? Trigger of CAPA?	PMS, CAPA
VIII, A101-108	Cooperation between Member States, MD Coopr. Group, etc.	n/a	
X, A123	Entry into Force and Date of Application	Define the timeline for your company/products	

MDR: Effects on QM-System (Annex)

Annex	Requirement/Change	Action	Process/SOP
I, CH1-3	General Safety and performance requirements More details will be provided in one of the following blog-posts in this series.	Old: 9 pages, 13 sections New: 14 pages, 23 sections Rewrite template «essential requirements»: NEW → GSPR Detailed Information about the content regarding labeling	Development Labeling
II	Technical Documentation More details will be provided in one of the following blog-posts in this series.	Own annex: clearly structured elements given Adapt new structure in a template as table of content without «own interpretation» (!!)	TD
III	Technical Documentation on PMS	Plan of PMS (Art. 84) PSUR (Art. 86) PMS-report (Art. 85)	PMS, TD
IV	EU DoC	Adapt DoC-template to the new structure	DoC

MDR: Effects on QM-System (Annex)

Annex	Requirement/Change	Action	Process/SOP
VI, Part A	Registration of devices and economic operators	Detailed information which data are required for EO (A31) and product (A29,4)	Development
VI, Part B	Data provided to the UDI Database	Detailed information which data are required for UDI-registration (A29)	Development
VI, Part C	UDI System More details will be provided in one of the following blog-posts in this series.	How to handle UDI: adapt requirements in the corresponding processes	Development, Labeling
VII	Requirements to be met by Notified Bodies	Read it, so you will know what they will ask for	
VIII	Classification rules More details will be provided in one of the following blog-posts in this series.	Implement the new requirements in your process Re-Assessement of all your products	Development
IX-XI	Conformity assessment More details will be provided in one of the following blog-posts in this series.	3 types of conformity assessments	

MDR: Effects on QM-System (Annex)

Annex	Requirement/Change	Action	Process/ SOP
XII	Certificates issued by a Notified Body	n/a	
XIII	Custom-made devices	If applicable: adapt your processes → traceability after production	
XIV-XV	Clinical evaluations Clinical investigations More details will be provided in one of the following blog-posts in this series.		Clinical Evaluation