Medical Device Consult ApS

Strandmøllen A/S

Netværksmøde omkring medicinske gasser

Tirsdag den 21 Januar 2020

- Overgangen til MDR – Hvad betyder det for vores hospitaler?
- Overgangen til MDR – Hvad betyder det for leverandøren?
- Anvendelsesområder: Fra hospital til sædbanker?
- Nye mekanismer : Databaser? Gennemsigtighed?
- Bag-ud kompatibelt? Skal der ændres noget for eksisterende set-ups hos leverandører/hospitalet
- Hvordan kan leverandører/hospitaler/regionerne bruge en ekstern partner til at risikovurdere deres udstyr

MDC
MEDICAL DEVICE CONSULT
MDC assists companies in meeting the European regulatory requirements

CV for Henrik Kvistgaard

- M.sc mechanical engineering from DTU in 1992, specialized in production and quality management

- Broad experience within MD & IVD business;
  - 1991-96: Boston Scientific A/S
    - Quality Engineer
    - QC-Manager
    - QA-Manager
  - 1996-1997: Scandimed ApS
    - QA-Manager
  - 1997-1999: Celwave RF A/S (Electronics)
    - Kvalitetschef
  - 1999-2006: NUNC A/S (ThermoFisher Scientific)
    - RA Manager
    - QA/RA-Direktør
  - 2006-2007: Radiometer Medical (Danaher Inc.)
    - VP Quality
  - 2007-: Medical Device Consult
    - owner

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MDC - Medical Device Consult ApS

MDC is a Danish based consulting firm founded in 1995 by Vivi Thulstrup.

MDC has specialized in assisting medical device and in-vitro diagnoatic companies in meeting regulatory and quality system requirements.

In 2007, Henrik Kvistgaard aquires MDC as Vivi retires

<u>Basically two main assignments;</u>

- Quality Management Systems – establishment and maintenance
- Regulatory compliance – technical files – establishment and maintenance

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MDC – Other services within QMS

- Specialist knowledge within;
  - Corrective- and preventive action
  - Risk Management according to ISO 14971:2019
  - Vigilance according to MEDDEV 2.12-1 and FDA MDR requirements

- Optimization of quality plans and - activities
- Internal quality audits and FDA MOCK-inspections
- Audits of outsourced manufacturing and sub-suppliers
- Accredited competence within sterilization
- Assist companies in ”defending” during audits and inspections.

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MDR 745/2017 – What is this?

- EU Commission defined a task force in 2010 with the aim to;
  - Strenghtening the safety and effectiveness of MDD and IVD (Artifical hips case in the early 2000's)
  - Modernising the AIMD, MDD and IVDD
  - Prevent fraud in the MD business (breast implant case in France…..)
  - Inforce/support innovation amongst EU MDD companies……(!)
- **Result;**
- MDD & AIMD is now combined into MDR 745/2017 – 336 pages !!
- IVD MDR 746/2017

MDR 745/2017 – some notes

- Approval in may 2017 – 3 years transition – May 27.2020
- Any current CE-certifications will expire after 4 years (2024).
- No significant changes to existing approvals are accepted after January 2020

- Considered worse to comply with than US FDA 21 CFR – we believe !!

- Considerable reinforcement of;
  - Supervisions of Notified Bodies
  - Conformity assessment procedures
  - Clinical investigations and clinical evaluations
  - Vigilance and Post Market Surveillance (PMS)
  - High standards of quality and safety = Risk Management
  - Requirements for class I manufactureres
  - Economic operators

- GHTF/IMDRF guidelines now referenced to gain global inforcement along with EU MDGC-Guidelines
  - Expect manufacturers to focus on US, Canada, and other markets before EU.

Definition

- Current MDD:

medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combi- nation, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of or compensation for an injury or handicap,
- investigation, replacement or modification of the anatomy or of a physiological process,
- control of conception,

New MDR

'medical device' means any instrument, apparatus, appliance, software, implant, reagent, material or other article intended by the manufacturer to be used, alone or in combination, for human beings for one or more of the following specific medical purposes:

- diagnosis, prevention, monitoring, prediction, prognosis, treatment or alleviation of disease,
- diagnosis, monitoring, treatment, alleviation of, or compensation for, an injury or disability,
- investigation, replacement or modification of the anatomy or of a physiological or pathological process or state,
- providing information by means of *in vitro* examination of specimens derived from the human body, including organ, blood and tissue donations,

The following products shall also be deemed to be medical devices:

- devices for the control or support of conception;
- products specifically intended for the cleaning, disinfection or sterilisation of devices.

Significant changes (or ”challenges”) for Manufacturers

- Software in its own will most likely be class IIa
- ”Non-Medical devices” are regulated as MD’s ?? – Annex XVI
- Nanomaterial – most severe assessment procedures similar to class III
- Many class I devices will be class IIa
- Risk Management - ISO 14971 – will it survive as is??
- Class I manufacturers must have a ”full quality management system”
- Risk management and clinical evaluation must be aligned
- UDI-labelling becomes mandatory
- Responsible person for regulatory compliance must be appointed (no longer ”Qualified person”)
  - Diploma, certificate or other formal qualification and at least 1 year in QA/RA
  - OR 4 years professional QA/RA experience with medical devices.
  - Competent authorities may introduce local rules…….
  - Micro and small enterprices need not to have their own. Could be a permant consultant.
- Reprocessing of single use device – such persons now becomes legal manufacturer
- Patient information requirements for implantable devices – Implant cards becomes mandatory
- EUDAMED – entrance transparence database (registrations, Vigilance…..)
- Class III clinical evaluation reports must compare device with possible alternatives
- Member states may add requirements on the Notified body
- Expert panel must review class III and class IIb active (drug admin or drug removal devices)
- Already CE-marked class III MD’s with no clinical trial need not to perform clinical !!
- NB’s will have a difficult time – in 2015 80 NB’s – it is expected that max 40 will be acredited to MDR (today we have 7-8!!)

Significant changes (or ”challenges”) for Manufacturers

- OBL / OEM will be challenged since all must share their technical file – you cannot rely on other mfg’s CE-Mark
- Common specification (CS) program from the commision
  - List of 80 CS’s – none is finalized yet
- CS overrules harmonized standards. These might not be enough any more.
- Technical files and certificates shall be retained for 10 years after taking the device off the market (implants 15 years)
- PMCF is now required for all classes of MD’s.
- Now specific requirements for the content of a QMS (chapter II of the MDR – looks like 13485)
- Technical file shall be provided to authorities upon request – in an official EU-Language(?)
- Much more responsibility of the Importers, distributors and the Authorized representative. Importers shall also be identified on the label or in a document accompanying the device.
- Declaration of conformity shall be updated regularily and translated into EU-languages (?)
- Very tightened requirements for Post Market Surveillance (PMS) and reporting to Eudamed database (not yet finalized…..)

Impact on Health Institute / Hospital

Article 5

Placing on the market and putting into service

1.A device may be placed on the market or put into service only if it complies with this Regulation when duly supplied and properly installed, maintained and used in accordance with its intended purpose.

2.A device shall meet the general safety and performance requirements set out in Annex I which apply to it, taking into account its intended purpose.

3.Demonstration of conformity with the general safety and performance requirements shall include a performance evaluation in accordance with Article 56.

4.Devices that are manufactured and used within health institutions, with the exception of devices for performance studies, shall be considered as having been put into service.

→ Hospitals becomes manufacturers!

Impact on Health Institute / Hospital

Article 1, clause 9;

This Regulation shall not affect national law concerning the organisation, delivery or financing of health services and medical care, such as the requirement that certain devices may only be supplied on a medical prescription, the requirement that only certain health professionals or health care institutions may dispense or use certain devices or that their use be accompanied by specific professional counselling.

Impact on Health Institute / Hospital

Regulation I, clause 30;

Health institutions (including Sperm-banks) should have the possibility of manufacturing, modifying and using devices in-house and thereby address, on a non-industrial scale, the specific needs of target patient groups which cannot be met at the appropriate level of performance by an equivalent device available on the market.

In that context, it is appropriate to provide that certain rules of this Regulation applies, as regards medical devices manufactured and used only within health institutions….

BUT WHICH RULES ???

Member States shall encourage, and may require, health institutions to provide information to patients on the use of reprocessed devices within the health institution and, where appropriate, any other relevant information on the reprocessed devices that patients are treated with.

Impact on Health Institute / Hospital

Regulation I, clause 38;

The reprocessing and further use of single-use devices:

The reprocessor of a single-use device should be considered to be the manufacturer of the reprocessed device and should assume the obligations incumbent on manufacturers under this Regulation.

Nevertheless, Member States should have the possibility of deciding that the obligations relating to reprocessing and re-use of single-use devices within a health institution.

In principle, such divergence should only be permitted where reprocessing and reuse of single-use devices within a health institution or by an external reprocessor are compliant with CS that have been adopted, or, in the absence of such CS, with relevant harmonised standards and national provisions. The reprocessing of such devices should ensure an equivalent level of safety and performance to that of the corresponding initial single-use device.

Especially for sperm-banks

- Sperm Banks are considered ”Health Institutes” (as a Hospital)
- Specimen containers are covered by the IVDR, taking effect in May 2022 (Class A, Low risk, self certifying)
- IVF-Devices are considered Medical devices class IIa (and has always been)
- Dishes, Pipettes, reagents, LAF-benches, Incubators are all affected by the MDR (class IIa, rule 2), leading to higher prices and possibly less products

- Hospitals must buy CE-marked devices – if they exist
- Sperm Banks will be affected by new MDR-requirements for Liquid Nitrogen and ISO standard requirements for Medical Gas Pipeline Systems.

MDR Overall impact on industry

- The term ”Economic Operators” has been defined;
  - (Manufacturers)
  - Importers
  - Distributors
  - Authorized representatives

- Must register with local Competent authority (Lægemiddelstyrelsen)
- Fees shall be expected
- Must participate in field safety corrective actions
- May be held liable for product non-conformities

- Impact:
  - Increased costs of product
  - Must have product liability insurances
  - Must implement traceability
  - Aut rep’s must participate in PMS activities
  - Aut rep’s must have copy of Manucaturers technical File
  - Less new devices on the market ?
  - Some devices has already been retracted from the EU Market

New Mechanisms

- Eudamed PMS reporting database (not finalized yet)
- 80 new Common Specifications (not published yet)
- Central registration database (not finalized yet)
- Central EU Vigilance database – similar to US ”Maude” (not finalized yet)
- UDI labelling requirements become mandatory
- Post Market Clinical Follow-up become mandatory
- Economic operators has far more product responsibility
- Manufacturers must appoint responsible person for Regulatory compliance
- Expert panels must review and clear class III and active class IIb devices

Compatibility with current systems build according to MDD

Healthcare institutes

No need to change existing installations and routines unless;

- MDR Annex I (General Safety and Performance Requirements) leeds to new requirements
- The MDR annex VIII changes the classification
- Common Specifications affects your devices
- Updates to relevant EN or ISO standards, i.e 7396-X, 9170-X…..
- You re-process single-use devices
- You build own devices (not allowed if CE-market device exists….)
- Must keep the UDI of implanted devices (trace to patient)

Manufacturers

The MDR has full effect and results in significant changes

- Products placed on the market is still OK and may be used
- CO2 Medical Gas may be classified as III according to rule 21 (MDD class IIa)
- Gas Pipe systems appear to maintain class IIa according to rule 2

Risk Management

- ISO 14971:2019 is harmonized against the MDD and must be used for risk assessments and requires;
  - Risk Management Plan
  - Risk Analysis and Control (RAC, FMEA, FMECA or other methodlogy)
  - Risk Management Report, including risk/benefit analysis
  - Presence of ”Expert”, relevant functions, medical competent person
  - Quite complex excercise which can result in needs for changes to existing devices
  - Join courses
  - Hire consultants
  - Involve suppliers

- Thank you