DHF Remediation
MDR Implementation
Combination Products
UDI Compliance

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# MDR Restricted Substances for Polymer Components

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## Swiss MPC is a Medical Device and Pharma Consultancy group based in Cham, Switzerland and Galway, Ireland.

Swiss MPC provides Medical Device and Pharmaceutical Consulting solutions to clients to support the fulfilment of their MDR, UDI, DHF & Tech-File requirements from concept to implementation.

**Full Project Execution & Staffing**
Swiss MPC will liberate you from the need of hiring and managing individual freelancers and therefore free your internal resources from unnecessary activity.

## Services

### Design History & Tech Files
*Remediation & creation for product compliance*

### Medical Device Regulation
*MDR Implementation from gap assessment to execution*

### Unique Device Identification
*UDI Compliance services for US/EU market*

### Combination Products
*Full compliance services for Combination Products*

# MDR requirements on Hazardous Substances

- General approach:
  - Risk reduction of substances being released from a device, by reduction of the content of those substances

*"Devices shall be designed and manufactured in such a way as to reduce as far as possible the risks posed by substances or particles, including wear debris, degradation products and processing residues, that may be released from the device."*

- Implicitly applicable regulations
  - MDR/2017/745 Regulation on medical devices
  - CLP/1272/2008 Regulation on classification, labelling and packaging of substances and mixtures
  - REACH/1907/2006 Regulation concerning the Registration, Evaluation, Authorization and Restriction of Chemicals
  - RoHS/2011/65 Directive on the Restriction of the use of certain Hazardous Substances in electrical and electronic equipment

# Groups of Hazardous Substances

**CMR / ED**

- Cancerogenic
- Mutagenic
- Toxic to reproduction
- Endocrine disruptors

- Biological origin material
- Nanomaterials

Present as an integral Part of the Device

Present due to exposure during manufacturing process (Adjuvants)

# Groups of Hazardous Substances

| CMR / ED | Biological origin material | Nanomaterials |
|---|---|---|

- Use restricted for
  - **Carcinogenic**, **mutagenic** or **toxic to reproduction** (CMR) Cat. 1A or 1B well as substances with **endocrine-disrupting (ED)** properties
  - Acc. Part 3 of Annex VI EC 1272/2008, and
  - Identified in "REACH" EC 1907/2006 (substances of very high concern list SVHC) – some substances have allowable uses
- If exceeding a maximum concentration of 0.1 % w/w in products that:
  - Are invasive and come into direct contact with the human body
  - (re)administer, transport or store - medicines, body liquids or other substances, including gases to/from the body
- If restricted substances are present above the threshold, justification* and identification on the Product Label and IFU is required

* Special justifications for Phtalates required (link)

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## Groups of Hazardous Substances

| CMR / ED | Biological origin material | Nanomaterials |
|---|---|---|

- EU 2017 / 745 (MDR) Annex I, Chapter 2, 13
  - Material of human origin (only if intentionally added)
  - Material of animal origin (depending on manufacturing process, can be excluded)
  - Material of other biological origin (e.g. Latex)
- Mainly related to adjuvants
- If these Materials are present, specific documentation on sourcing, handling, and traceability of the material are required in order to assure patient safety.
- Human or animal tissue devices (non-viable) are Class III (Rule 18)
- Generally unintentionally added Biological materials can be reliably removed by final cleaning steps.

## Groups of Hazardous Substances

| CMR / ED | Biological origin material | Nanomaterial |
|---|---|---|

- EU 2017 / 745 (MDR) Annex I, Chapter 2, 10
  - Nanomaterials (more than 50% of particles 1 – 100 nm)
  - Risk Class assignment dependent on internal exposure (Rule 19)
  - Particle assessment with analytical methods only with high effort
  - Risk assessment based on SCENIHR report:
    Particle release
    Type and Duration of contact
    Particle distribution
    Toxicological assessment

## Groups of Hazardous Substances

- RoHS 2011/65
  - Not directly referenced in MDR
  - Only for electrics and electronics
  - Does not depend on patient contact
  - Concentration maximum of 0.1% (Cadmium 0.01%)

Lead (Pb)
Mercury (Hg)
Cadmium (Cd)
Hexavalent chromium (Cr6+)
Polybrominated biphenyls (PBB)
Polybrominated diphenyl ether (PBDE)
Bis(2-ethylhexyl) phthalate (DEHP)
Butyl benzyl phthalate (BBP)
Dibutyl phthalate (DBP)
Diisobutyl phthalate (DIBP)


# Hazardous Substances

## Implications for Manufacturers

| | | CMR/ED | Biol. | Nano | RoHS |
|---|---|---|---|---|---|
| Assessment of Risk & Patient Exposure | Manufacturers are responsible to assess the general risk of a device and its level of invasiveness for the patient. Based on this, Manufacturers will request Material and Substance information from Suppliers | | | | |
| Assessment of Hazardous Substances | Based on the Supplier information and with support of the Supplier, the Manufacturer will assess the concentration of hazardous substances | | | | |
| Justification if Hazardous Substances are present | If Substances are present / present above the threshold a multi stage evaluation and justification process needs to be executed by the supplier, or the product needs to undergo changes | | | | |
| Registration of present Substances in EUDAMED | If CMR/ED Substances are present above the threshold, the Manufacturer needs to register the presence of these substances with the record of the device concerned in the European Database on Medical Devices (EUDAMED) once active | | | | |
| Labeling of present Substances (Product Label & IFU) | If Substances are present / present above the threshold, the Manufacturer needs to disclose this information on the device label and in the Instructions for Use (IFU) | | | | |
| Impact on Unique Device Identification System | If changes are made to a device that newly introduce a restricted substance, or a present restricted substance has been overlooked during assessment, a new Device Identifier will need to be assigned through the UDI system | | | | |

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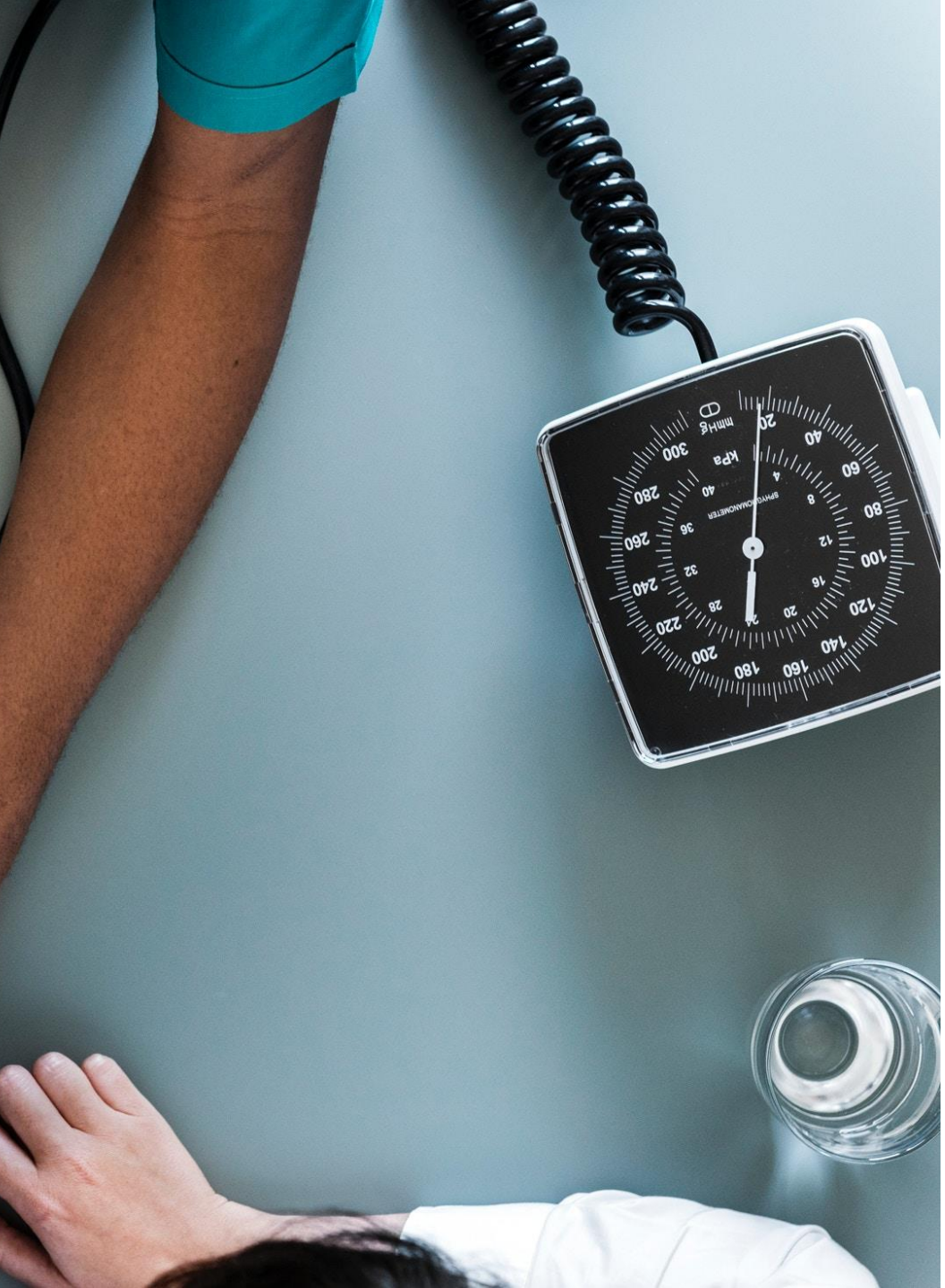
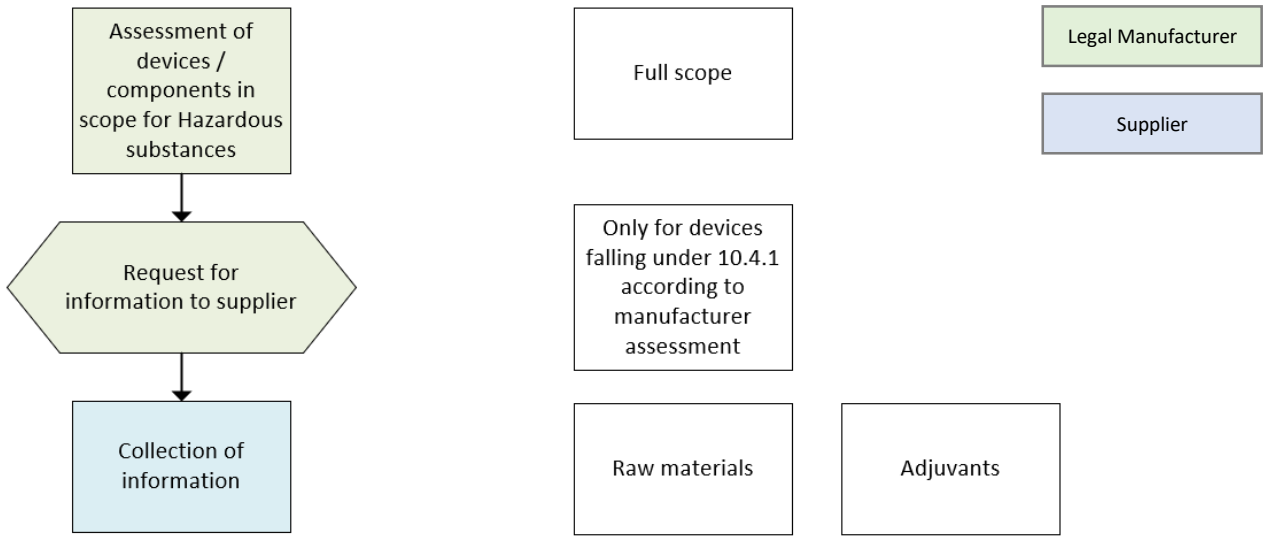


# Assessment workflow

## Manufacturer – Supplier




- In order to allow for a efficient process, Information on raw materials and adjuvants should be collected routinely in a master list.

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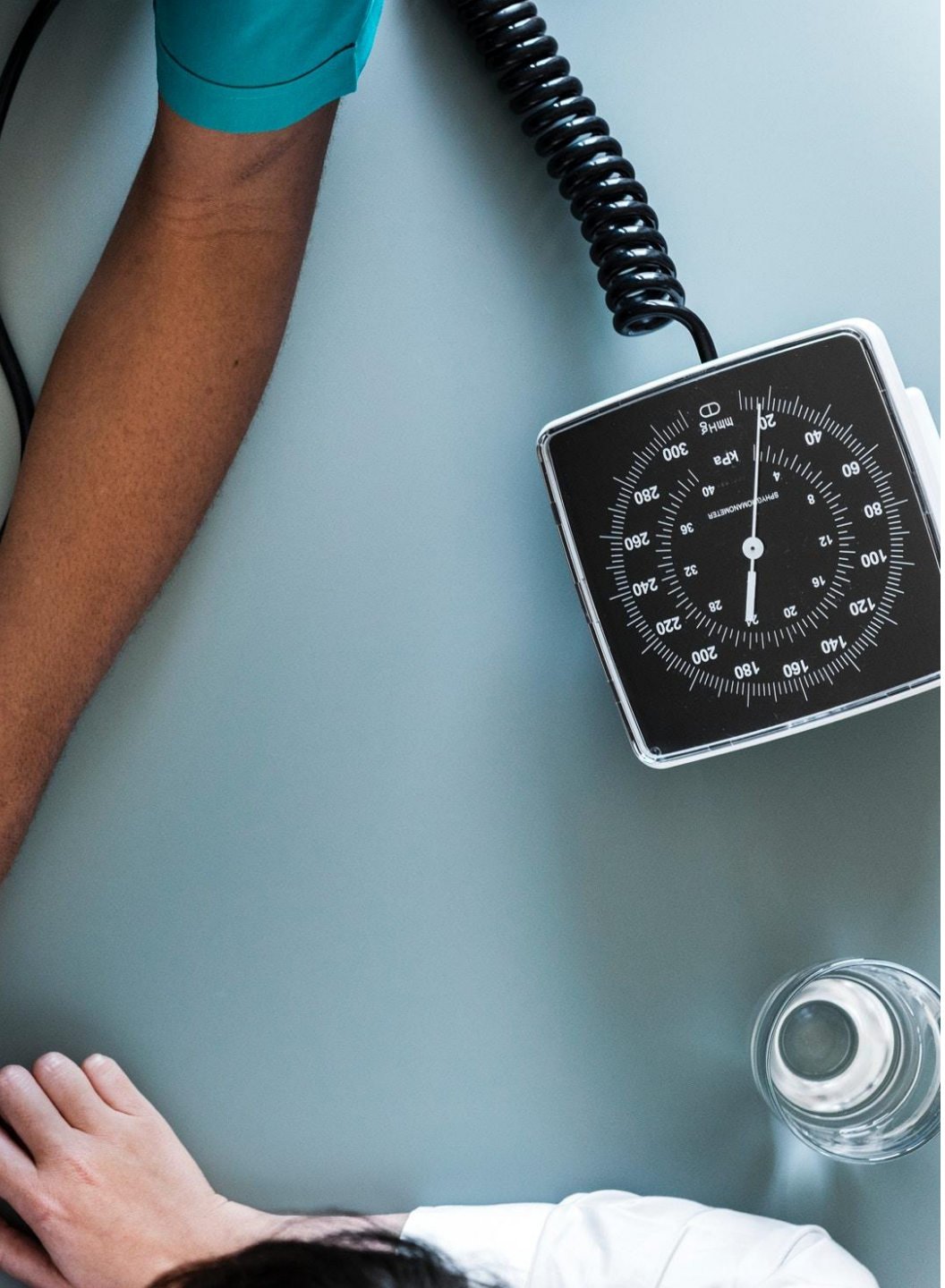

## Collection of Information by Suppliers

- Proof / certification of substance content / compliance
  - Polymeric raw materials: SDS
  - REACH / RoHS: SDS or Certificate / Proof of Compliance
  - Nano & Biological material: absence declaration
- Substances names should be supported by at least one or more of the following:
  - CAS or EC number (mandatory)
  - Chemical Symbol
  - Other agreed abbreviations (e.g. DEHP)

## Conclusion

- CMR/ED analysis will only be requested for invasive devices acc. Annex I 10.4.1
- Biologics, Nanomaterials and RoHS status should be routinely monitored and recorded
- Information and specifications on manufacturing processes and adjuvants need to be recorded acc. Annex II 3b
- The establishment of robust and efficient procedures for collection and assessment of substance information is essential

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# Thank you very much for your attention


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