Managing EU MDR, Hazardous Substances

Chemical Services for Medical Devices

www.tuv.com

TÜVRheinland®
Precisely Right.

1 Why Chemical Checks for Medical Devices?

HAZARDOUS SUBSTANCES ARE LEGALLY REGULATED FOR MEDICAL DEVICES IN THE EUROPEAN UNION.

"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, which may be released from the device."
((EU) 2017/745 (EU/MDR) Annex 1, Chapter II, Section 10.4.1)

Focus acc. to EU/MDR:

- Substances which are carcinogenic, **mutagenic or toxic to reproduction ('CMR')**, of category 1A or 1B, in accordance with Part 3 of Annex VI to Regulation (EC) No 1272/2008 of the European Parliament and of the Council
- Substances having **endocrine-disrupting** properties
- **Phthalates**

"10.4.2. Justification regarding the presence of CMR and/or endocrine-disrupting substances
The justification for the presence of such substances shall be based upon:
(a) an **analysis** and estimation of potential patient or user exposure to the substance; …"
((EU) 2017/745 (EU/MDR) Annex 1, Chapter II, Section 10.4.2)

All further risk analyses or changes in design are based on reliable knowledge about the presence or absence of hazardous substances.

FURTHER EUROPEAN LEGISLATION ON HAZARDOUS SUBSTANCES THAT ARE ALSO RELEVANT FOR MEDICAL DEVICES:

- **RoHS** (DIRECTIVE 2011/65/EU on the restriction of the use of certain hazardous substances in electrical and electronic equipment)
- **POP** (REGULATION (EU) 2019/1021 on persistent organic pollutants)
- **REACH** (REGULATION (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals)
- **CLP** (REGULATION (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures)

2 Risk Assessment

The possibility of the presence of hazardous substances in the materials of medical devices should also be considered as part of risk management in accordance with Annex I of the MDR.

- Inherently a part of the base material
- Additives to enhance, improve, color, protect, manufacture the material
- Petroleum- Release agents that remain in the material
- Softeners
- UV stabilizers
- Adhesives
- …

WITHOUT CHEM. ANALYSIS, THESE SUBSTANCES OFTEN ARE UNKNOWN TO THE OEM.

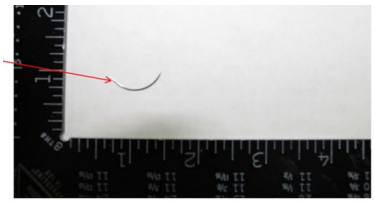
- **Proprietary formulations:**
  Known to your organization, not known to downstream users. Typically not included in public documentation (MSDS, Registration Dossiers, Formulas)
- **Off-The-Shelf (OTS) components:**
  Requires full data disclosure, or testing (declarations based on supplier risk assessment) However formulas can change, part numbers remain the same
- **Custom Built components:**
  Contract Manufacturers (Auditing, part control, risk assessment) SME's & small shops have limited resources for testing, issuing declarations etc.

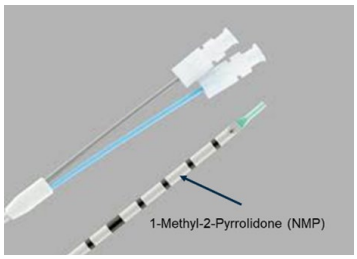
3 Examples from the Field

DEHP found >12% in tubing labeled "DEHP FREE" from supplier

Working with the client we discovered that the supplier was only using one production line for manufacturing both DEHP and non-DEHP tubing.
Meanwhile the client has done multiple lot# testing with us to ensure the lines are properly disinfected before production.
The client is also considering changing supplier.

Elemental Cobalt in Surgical Stainless Steel Needles
0.24%

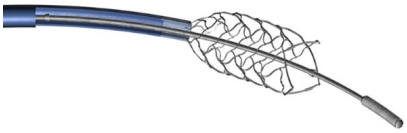


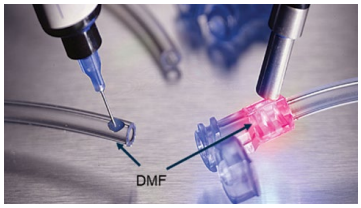


NMP found in Medical Lead
0.17%

Typically used in the manufacturing process and not intended to be part of the finished product, yet sometimes residual amounts can be found.

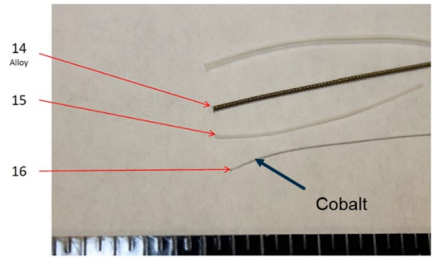
0.14 % Cobalt Salts found in Medical Stent Delivery Lead
Cobalt salts are commonly used as blue pigmentation in polymers.





N,N-dimethylformamide (DMF) found in the adhesive bonding tubing and leads together.

0,25% Cobalt found in guide-wire



4 REACH/RoHS/CLP + MDR (The Connection)

Most of the hazardous substances are regulated not only in the EU/MDR, but also in other legal regulations, e.g. the one mentioned above.

For this reason, **we combine the requirements of applicable legal regulations** in test programs for fast and simple proof of conformity and use synergies to your advantage.

- RoHS 4, 6 and 12 deal with additional phthalates found in other regulations (CalProp 65, REACH, MDR).
- REACH SVHC Candidate List includes Endocrine Disruptors (ED) hazardous to Human Health.
- MDR substances include Current REACH 2XX substances and others.
- In reality, the REACH Candidate list, Article 67 (REACH restricted list) together with the CMR substances from categories 1A and 1B of the CLP list make up the chemicals of concern according to MDR.
- Since some of the substances in the CLP list are included in REACH, analysis of both is recommended.
- REACH / RoHS should be managed currently for all products entering the EU, so adding additional substances to your due-diligence efforts would be a good way to control this.

REACH Candidate List (0.1%) is the threshold for communication to downstream users (Action).

SCIP-database entries require a good technical documentation for hazardous substances.

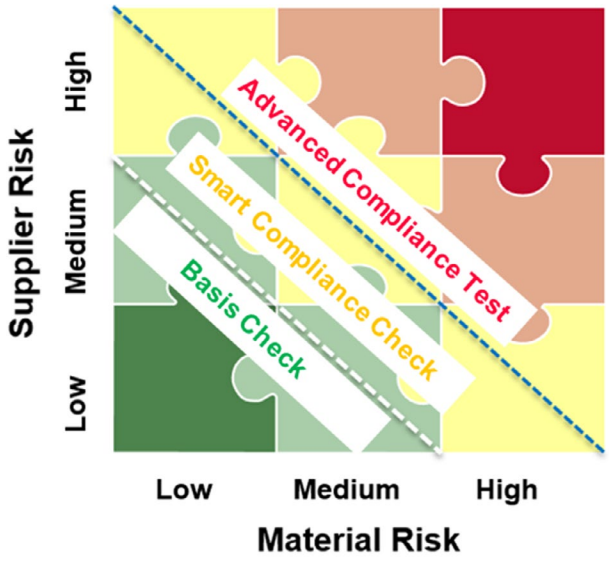
5 How can you Demonstrate Compliance?

Auditors are aware of Annex 1, Chapter II and will inquire as to how you will demonstrate compliance.Most auditors have been trained in biocompatibility and have extensive knowledge of endocrine disruptors and phthalates. Specific questions on list of substances, test methods and laboratory accreditation will be asked.

TUV MEDICAL DEVICE-SCREENING PROGRAM

The proactive TUV screening programs use state-of-the-art, recognized and proven analytical methods to identify potentially harmful and banned chemicals in medical devices.

Based on the technical information available to you about products, components and materials of your medical device as well as their origin, we offer defined screening programs to complement your risk analysis, enabling you to demonstrate your due diligence as well as compliance with regard to hazardous substances.



SUPPLIER RISK:

How well do you know your supplier, his quality standards, the type of production, the quality assurance measures; the training level of the personnel, etc.? Is it already a long-standing business relationship or is it a new supplier? Have there already been complaints? etc.

MATERIAL RISK:

How well is the supplied material or product documented? Are there associated test reports confirming compliance with legal requirements, including those relating to hazardous substances? How old are the test reports and do they belong to the actual material batch? How high do you estimate the variation range of the material? Do the materials come from a brand manufacturer? etc.

6 Our services, your advantage

FIVE WAYS IN WHICH WE ADD VALUE TO YOUR PRODUCTS AND SERVICES:

- We share our 150 years' worth of experience in the market
- We strictly abide to the latest and highest standards
- We are renowned for protecting and adding recognition to your brand
- We create ideal conditions for higher performance
- We promote and accomplish worldwide sustainable growth

TAKE THE NEXT STEP

Would you like to find out more about our services for the chemical testing and evaluation of your medical devices? You can find our entire service portfolio on our website.

Or take the next step and request your non-binding offer today!
We will accompany you on the way to market launch.

CONTACT NOW

TÜV Rheinland LGA Products GmbH
Tillystr. 2, 90431 Nuremberg
Tel. +49 911 655 5225
service@de.tuv.com

www.tuv.com

TÜVRheinland®
Precisely Right.