

Blood Bag Manufacturing and the MDR

Your partner for navigating regulatory challenges in blood bag production and ATMP storage

The European Union's Medical Device Regulation (MDR) has introduced rigorous requirements for medical device manufacturing, including blood bags. Of particular note are **Annex I, Chapter II, 10.4 (Substances)** and **Annex I, Chapter I, 1 (General Requirements)**. In addition, the Paul Ehrlich Institute (PEI) requires **DEHP-free systems** for the production and storage of blood components and stem cell preparations.

These requirements often present conflicts for manufacturers: ensuring product safety while adhering to substance restrictions poses unique technical and regulatory challenges. Valicare is your trusted partner in addressing these complexities with precision and expertise.



Our services

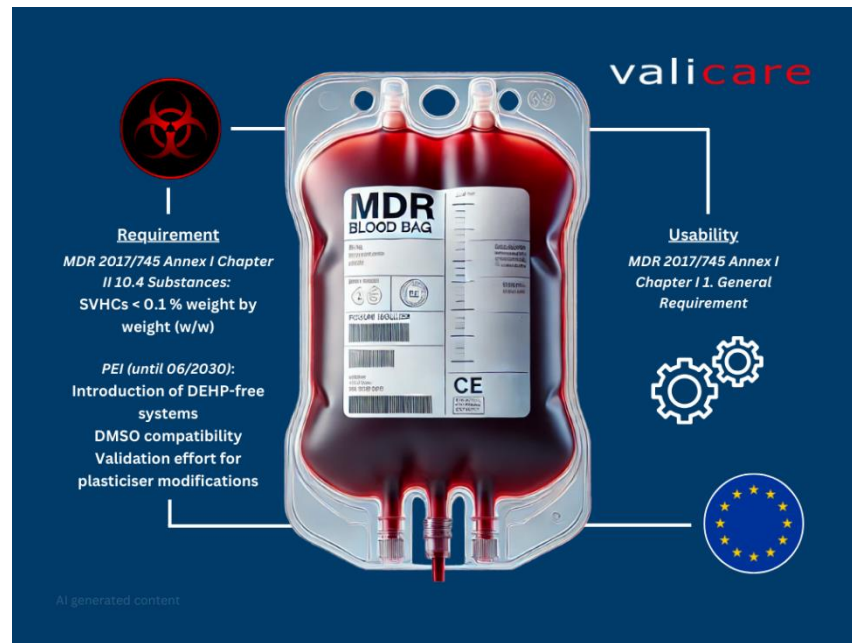
- Regulatory expertise: Support in interpreting and implementing MDR Annex I requirements
- Substance risk assessment: Evaluation of phthalates and other SVHCs in compliance with Annex II Chapter II 10.4
- Technical documentation: Creation of MDR-compliant technical documentation
- Risk management strategies: Alignment of product safety and performance with regulatory requirements
- Coordination and execution of material compliance testing

Our expertise

- In-depth knowledge of MDR requirements for medical devices and substances
- Decades of experience in medical device manufacturing and regulatory compliance
- Interdisciplinary teams of scientists, engineers, and regulatory specialists
- Proven success in navigating complex regulatory challenges

Your benefits

- Proactive management of regulatory risks
- Assurance of compliance with MDR requirements
- Streamlined processes for faster market access
- Enhanced product safety and performance compliance



Contact us to address the unique challenges of blood bag manufacturing successfully and in compliance to the MDR. Valicare is your trusted partner for navigating these complexities!



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