RAUMEDIC ECC

Products for extracorporeal circulation

Reliably safe

- Manufacturing according to WHO-GMP guidelines for medicinal products and quality assurance
- Production, quality control and documentation according to international quality standards (DIN EN ISO 13485)
- Documentation allows reconstruction of every single process for up to 7 years later
- On request: certificate of performed tests according to pharmacopoeias, international standards and FDA requirements

For our ECC products, we go the extra mile:

The basic prerequisite for the suitability of the polymer material formulation in RAUMEDIC's ECC products is the passing of **biological-toxicological requirements.**

- Cytotoxicity test in compliance with DIN EN ISO 10993-5
- Implantation test, system toxicity test and intradermal test in compliance with USP Class VI
- Pyrogen test in compliance with DAB E. Ph.
- Hemolysis test according to DIN EN ISO 10993-4
- Chemical biological toxicology tests in compliance with DIN EN ISO 3826
- LAL test in compliance with USP and E. Ph.

Silicone Pump Tubing

The silicone pump tubing ensures precise and consistent pumping accuracy for the user. RAUMEDIC excels in meeting stringent tolerance requirements.

- **Ideal pump tube: optimal strain and elasticity values as well as excellent resilience due to cross-linked elastomers**
- **Soft blood pulsation and minimal hemolysis, as the tubing remains soft and flexible regardless of blood temperature**
- **Inert material properties, no low-molecular components that could lead to undesired interactions**
- **Compatible with all common sterilization methods**

Blood Circulation Tubing

RAUMEDIC blood circulation tubing made of DEHP-free PVC (“noDOP“) is phthalate-free, which is of great importance in the medical and pharmaceutical industry, as phthalates are considered harmful and fall under the REACH regulation.

- **Improved hemocompatibility**
- **Reduced plasticizer migration (order of magnitude 1/100 gg vs. DEHP or DINCH)**
- **Implantation tests according to USP Class VI**
- **Own RAUMEDIC quality level “ECC”: highest safety standards for the critical application area**

Oxygenator Technology

Heat exchanger mats and tubing made of polyurethane (PUR) for use in extracorporeal circulation, cardioplegia, and long-term applications, such as ECMO or ECLS.

- **Made of polyurethane (PUR) – the material with the best blood compatibility among all thermoplastics**
- **Without plasticizers – no migration possible**
- **Better thermal conductivity than PET: allows for smaller surface areas and more compact designs**
- **Can be manufactured in individual geometries with regard to width and fiber density as well as fiber size**

Tube Connectors / Connectors Made of Polycarbonate (PC)

Matching connectors – made of polycarbonate (PC) – for cardiosurgical tubing

- **Made of shatterproof polycarbonate (PC)**
- **Injection molded from a single mold – smooth transitions, no bonding**
- **Prevents air infiltration through mold release seams behind the first tubing connection ring**
- **Fewer thromboembolic complications due to short design and low surface area**

All from one single source

Custom Developments

Do you have a product idea? RAUMEDIC accompanies you – from the product concept through material selection and design – all the way to manufacturing.

Global Service

What can we do for you?

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