

# ITV Denkendorf Produktservice GmbH



Knitting machine for the production of medical meshes

## Your partner in development and production of polymer- and textile-based medical devices:

- OEM-Manufacture of medical devices and their pre-products
- Contract based development of new medical devices
- Process Scale-Up & Technology Transfer
- Accredited chemical, textile and biological test laboratories

ITV Denkendorf Produktservice GmbH (ITVP) is founded in 2001 as a 100% subsidiary of DITF (German Institutes of Textile and Fiber Research Denkendorf). The main focus lies on application-oriented development and production of textile-based implants like e.g. sutures and meshes. ITVP is a reliable partner and supplier for industrial companies. ITVP is certified according ISO 13485 for the development and production of polymers, pre-products and devices for medical applications, but is not actively marketing medical devices for the final consumer.

Besides industrial contract research, ITVP conducts public founded projects with various topics including nerve regeneration, wound closure systems, textile implants for stent grafts and for intervertebral disc injuries.

## Development and production of medical devices

ITVP offers development, production and testing of medical devices along the whole process chain from polymer over processing up to the product to industrial partners. Our partners are responsible for certification and marketing of final products. Therefore polymerization reactors for chemical production of polymeric raw materials, especially absorbable and non-absorbable biomaterials in clean-rooms are available. The processing takes place on extruders, stretching-, braiding-, weaving- and warp-knitting machines.

ITVP offers to industry customized solutions, especially for absorbable polymers. On the basis of the monomers glycolide, lactide, trimethylene carbonate and  $\epsilon$ -caprolactone special polymers (homopolymers, random copolymers, block-copolymers) with different properties (elongation, elasticity, degradation behavior) are synthesised and processed in clean-rooms ISO class 8. Medical products which were developed by ITVP in cooperation with DITF and industrial partners, are successfully used worldwide:

- Surgical sutures and ligaments
- Vascular prostheses
- Stents for use in trachea and oesophagus
- Hernia meshes
- Foils for adhesion prophylaxis
- Membranes for the treatment of severely burned

## Accredited test laboratories

ITVP offers a series of accredited chemical and biological tests. Most of the tests are accredited according DIN ISO 17025 and underlie the supervision of the Deutsche Akkreditierungsstelle (DAkkS).

Another focus is the skin tolerance test for textiles. In these effect-related tests extractables from textiles are absorbed by a contact gel simulating the skin. Through transfer onto a cell culture that is sensitive towards harmful substances, the behavior of the cells in contact with the extractables is analyzed and evaluated. This test, executed in accordance to standards for medical products, is highly sensitive.



### Biology (cells, cytotox)/Skin tolerance

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## Services:

- Development and production of medical products in clean-rooms
- Synthesis of biocompatible polymer materials (200 g / 1–5 kg / large-scale)
- Processing of polymers to medical products according to processes of textile and plastics engineering
- Accredited test laboratories e.g. for chemical tests: GC-MS, FT-IR / UV-Spectroscopy, Differential Scanning Calorimetry (DSC)
- Testing of the skin tolerance of textiles
- Biological tests such as cytotoxicity tests and testing of the antibacterial effect

### ITV Denkendorf Produktservice GmbH

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Accredited laboratory by DAKKS according to DIN EN ISO/IEC 17025. The accreditation is valid only for the scope listed in the annex of the accreditation certificates D-PL-17474-01-00 respectively D-PL-17474-01-02.