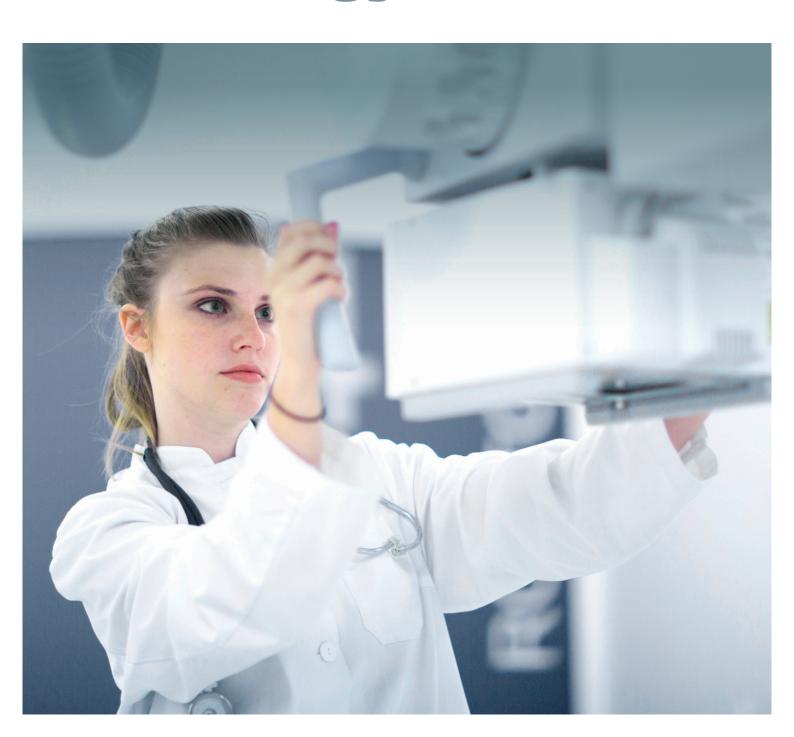


# Safety in medical technology

Design and Production Services



# Sustainably verified processes according to ISO 13485

#### **Product & Application Design**

- Design with project and risk management according to medtech standard ISO 14971
- > Application development
  - > DFX Design for Excellence
  - > Software and hardware development
  - > Design and construction
- > Support in the field of EMC and approvals (CE, Electrosuisse, VDE, T.V, UL, CSA)

#### **New Product Introduction (NPI)**

- > Industrialisation phase:
  - > Validation of the new products by means of checklists and release processes
  - > Determining of relevant production data
  - > Production technology optimisation (DFX)
  - > Definition of test concept (verification)
- > Prototyping for sample and pre-series

#### **Supply Chain Management**

- > Consistent traceability of materials management in accordance with a mutually agreed concept
- Selected procurement channels; delivery programme at technology leadership level (products built to medical technology specifications with CoC)
- Active supplier management and strategic partnerships around the world (evaluation and development programs)

#### **Production**

- > Certified production competences in different areas
  - > Electronic components & assemblies
  - > Mechatronics (incl. device and system construction)
  - > Cable assemblies

- > Batch sizes from 1 to > 1 million pieces
- > Production flexibility through international positioning
- > Production compliant with IPC 610 class 2 and 3
- Conducting of specific customer tests (optical, electrical & X-ray) and environmental simulations

#### Life cycle services

- > Life cycle cost monitoring:
  - > Component engineering
  - > Increased efficiency in production
  - > Obsolescence management and redesign
- > After-sales services:
  - > Repairs and spare parts management
  - > Software update
  - > Long-term stock-keeping
  - Servicing, calibration and maintenance of specific production media
- > End-of-Life service:
  - > Waste management
  - > Management of certification (discontinuation)
  - > Data archiving/data transfer

#### **Quality without compromise**

- > NPI and production processes in Europe, Asia and the Americas are ceritified according to ISO 13485
- > Consistent process control
- > Testing technology (verification)
- > Securing product & functional reliability (validation)
- > Traceability for mutually defined components
- > Documentation (specification verification)

We always check and conduct our qualified processes in line with regulatory requirements and as described in the jointly reached QA agreement. This can be verified by audits on your part or by external conformity assessment bodies.

#### **GPV's medical technology specialists**



GPV has medtech specialists in Asia, Europe, and the Americas

>

GPV meets the highest standards of development, production and system integration with infrastructure oriented to medtech.

GPV has sites in Asia, Europe and the Americas certified according to ISO 13485 and we offer you cost-optimised total solutions for the entire life cycle of your application.

We look forward to serving you.



### **About GPV**

## Many years of experience in medtech and related medical areas

The know-how and production services of the GPV sites are mainly in demand for Class I and IIa/b medtech products, and cover a very wide range of applications and application areas.

Even in these specialist areas, the GPV Group can offer the whole range: from development to series production, as well as from electronics to the complete device.



#### **Size**

8,000 employees, revenue: EUR 796 million (2022 guidance), around 180,000 m<sup>2</sup> production area, 52 SMT-lines and 19 sites.

#### **Locations medtech certified ISO 13485**

- > Asia:
  - > Electronics Thailand
- > Europe:
  - > Cables Slovakia and Austria
  - > Electronics Denmark
  - > Electronics Switzerland
- > Americas:
  - > Electronics Mexico





#### **Services**

Vertically integrated system manufacturer with the following expertise profiles:

- > Product & Application Design
- > Cable assembly
- > Mechanics
- > Mechatronics and box-build

#### **Engineering**

Our 150 specialists, engineers and technicians support your development success by catering for your demands throughout the entire product life cycle. With their specialised competencies, they create optimum solutions in diverse applications, such as: electronic design, embedded software, high frequency and communication technology, design and construction of testing systems, support and assistance for various approvals, and classic box-build design.

#### **Scaling**

From batch sizes of one (prototypes) to over one million, we are happy to serve you with state-of-the-art production concepts. We specialise in a wide range of products (high mix) and provide any batch sizes within this range at our international production sites.







GPV is committed to ensuring that our customers accomplish more. We do this by building strong and trusting partnerships based on responsible and honest cooperation.

We acquire comprehensive insights into our customers' needs and industries, and we manage advanced and stable product processing, relying on our strong technological knowledge.

#### Stable. Specialised. Global.

In everything we do, we focus on creating value for our customers, and our approach is supported by the strong spirit of our organisation. As such, we always strive for a timely delivery of faultless, secure and functional products and services that fulfil the expectations and requirements of our customers.

> gpv-group.com



#### Headquarters

GPV Group A/S Lysholt Allé 11 DK-7100 Vejle Denmark

#### Europe

GPV Cables AT (F) Frankenmarkt, Austria

GPV Cables AT (R) Rottenmann, Austria

GPV Electronics DK Aars, Denmark

GPV Mechanics DK Tarm, Denmark

GPV Electronics EE Elva, Estonia

GPV Electronics FI Lohja, Finland

GPV Electronics DE Hildesheim, Germany

GPV Cables SK Hlohovec-Šulekovo, Slovakia

GPV Electronics SK (H) Hlohovec-Šulekovo, Slovakia

GPV Electronics SK (N) Nova Dubnica, Slovakia

GPV Electronics SK (P) Piestany, Slovakia

GPV Electronics SE Västerås, Sweden

GPV Electronics CH Mendrisio, Switzerland

#### Asia

GPV Electronics CN (B) Beijing, China

GPV Electronics CN (S) Suzhou, China

GPV Electronics TH Bangkok, Thailand

GPV Mechanics TH Bangkok, Thailand

GPV Electronics LK Kochchikade, Sri Lanka

#### **The Americas**

GPV Electronics MX Guadalajara, Mexico

