



CONTRACT ENGINEERING

DEVELOPING
THE SOLUTION
YOU NEED



GENERAL INFORMATION

Start getting an idea of the LRE medical process

From the initial idea to the market ready innovation it's one exciting journey. Our state-of-the-art development process eases the way to game changing innovations. Find out more about the way we work:

WHERE THE PROJECT BEGINS

With LRE, an intensive and successful partnership usually begins with this idea. Because just as all departments are interlinked with each other, we also link our customers with each of our departments. This creates a close cooperation, characterized by a morphological approach that connects further ideas, input, feedback and optimization processes towards the realization of the ideal diagnostic device.

PROVIDING SOLUTIONS HOLISTICALLY

Along with the idea wishes, requirements and the general framework are presented. Our experts from the systems engineering and production engineering departments analyze the requirements and clarify the feasibility of the project.

This is the starting point of the realization process, in which we take all elements, parameters, and possible solutions into considerations. What follows is the generation of comprehensive solution approaches, which are presented using a decision matrix for feasibility and cost-effectiveness.



SYSTEMS ENGINEERING

Experience our holistic approach

From the smallest component to the synergy of all parts to the finished, state-of-the-art diagnostic device: the systems engineering department is responsible for the holistic development of new products. This includes full consulting support throughout the entire product life cycle, e.g. through optimization processes initiated by input from other departments.

TRANSLATING CLINICAL REQUIREMENTS INTO PRODUCT SPECIFICATIONS

A thorough understanding of the customer's requirements regarding application, end user needs and business processes supports the next levels of requirements:

- Determination of the functionality of the final solution
- Detailing the specifics about how the solution will be created to achieve the design goals in a technical specification and determination of the scope of work and development tasks.

DEVELOPMENT AND DESIGN

The great strength of our systems engineering department is the deep systematic understanding and approach within the topic. Our development experts are thus able to define the requirements of the overall system in its individual areas in order to bring the big picture together even in the most limited space. This ability of highly integrated miniaturization is a significant quality that we achieve through sophisticated design and extensive engineering knowledge.

WEIGHING FEASIBILITY AND COSTS

An important component in the comprehensive development and planning of the product is to balance feasibility and implementation costs. To this end, we present our clients a decision matrix with several realization routes that represent the best possible options within the budget. In this way we ensure that our customers always receive the best individual solution according to their budget plan.

At the same time our experts make sure that all components are state-of-the-art. It is also made certain that each individual part is available for a long time at our suppliers. In this way, we not only produce high-quality products, but can also secure that they can be manufactured and supplied in continuity.



PRODUCTION ENGINEERING

Learn how we ensure excellence and efficiency

When it comes to precision and quality it's a pretty good idea to turn to a German company. But this is not a cliché. We are always striving for excellence and efficiency, because it's a necessity in our line of work. Learn more about how we ensure both.

CONNECTING IDEA AND REALIZATION

The production engineering department is the decisive interface between the product idea and its realization. Accordingly, the production engineering department links development (systems engineering) and production. As the production engineering department provides all specifications for the creation of the production line, which is then subject to strict validation controls, it is also the direct contact for production.

LEAN EFFICIENCY FOR INDIVIDUAL PROJECTS

Efficiency all along the line. This is what the production engineering department creates. This is where customer-specific product requirements are transformed into a dynamic, lean optimized process ready for production. After all, each individual customer request requires a corresponding implementation of the production technology within the production line.

With our competence and experience, we ensure that the specifications are always met and the quality is always first class.

The extensive range of tasks and services is furthermore divided into two areas: mechanics and test engineering. Both fulfill essential tasks in their areas.

CASE SCENARIO COST EFFICIENT PRODUCT DEVELOPMENT: HANDHELD DEVICE FOR POC AND IVD SCENARIOS

For decades LRE Medical has partnered up with major corporations in the area of diagnostics. So, topics like cost and time efficiency come as no surprise to us, when we are asked to develop innovative devices that change the game. Being efficient is pivotal in our line of work. |

In the course of this project we realised a handheld device in combination with a fully integrated cartridge system for a high sensitive Immunoassay Platform. We solved the customer's challenges with a magnet-induced signal amplification and fluorescence detection with high positioning accuracy, high module integration and manageable manufacturing costs. |



Creating solutions. Improving lives.

LRE Medical combines technological, engineering and consulting competencies to create products that bring patients and diagnostic instruments into immediate proximity. In doing so, we foster the continuous advancement of diagnostics and measurement systems and, thus, help the well-being of people worldwide.

With our wide range of expertise that covers the complete product life cycle, we develop tailor-made products and produce them in small to medium-sized batches.

OUR PURPOSE OF PROFICIENCY

We are here to help. This simple mindset is a defining factor of our daily doing and conduct. We pride ourselves in providing our customers reliably with excellent products that positively impact people worldwide. Likewise, this readiness to help and to cooperate permeates LRE internally, making each employee a driving force behind our collaborative success.

LONG-LASTING, INTERNATIONAL IMPACT

We are here to stay. Our ability to deliver long-lasting quality and to continuously use and implement the latest technologies has established us as the long-term partner of trust for many companies. Together we push the boundaries and realize the progress of diagnostics on an international scale.

INTEGRATED EXCELLENCE

We are here for you. Every project and product we take on is developed and manufactured from the ground up to the requirements and exact specifications of our customers. In order to master this high degree of project individuality, our departments work closely together – from the first consultation to the product-optimizing feedback within the after-sales service process.


CON TACTS

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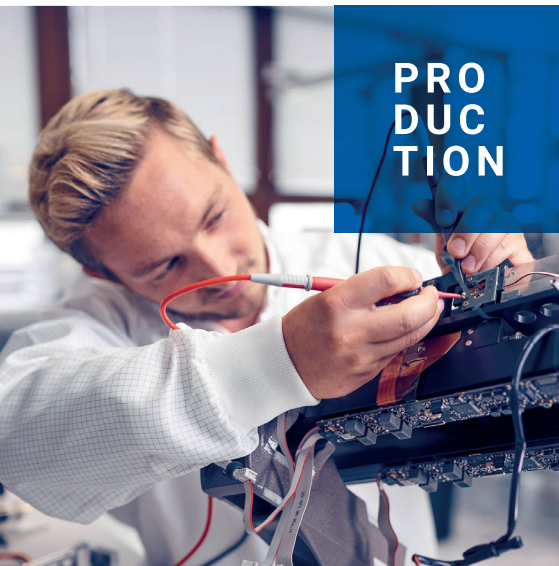
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A man with a beard and short dark hair, wearing a white lab coat over a blue collared shirt, is focused on working on a complex medical device. He is using a green-handled screwdriver. The device has various wires and components. The background is a blurred laboratory or factory setting with shelves and equipment. The image is overlaid with a large yellow and grey diagonal graphic.

SYNERGETIC PRO DUC TION

REALIZING
THE SOLUTION
YOU NEED



GENERAL INFORMATION

Meet your future production partner for healthcare devices

From the smallest component to the ready-to-use diagnostic device that provides health care to people around the world. In our production department our high quality diagnostic devices are manufactured in meticulous, concentrated work. Various technologies find their place here within miniaturized end devices.

PRODUCING NEXT-GENERATION DIAGNOSTIC DEVICES

We produce customized, specification-accurate, miniaturized and highly integrated machines that set standards in terms of quality, reliable precision and compact design. These products are either developed by LRE and consecutively manufactured at LRE or externally developed and transferred to LRE manufacturing. In both cases our claim to the highest customer satisfaction is always the guide to our efforts.

Our holistic value chain begins extremely early and is very detailed with the combined specifications of quality assurance, systems development and product engineering. Alongside this extends our enormous vertical range of production, which stretches from the printed circuit boards to the assembly of the finished, 100% tested - all validated meeting customers' quality requirements and supporting customers' regulatory filing.

INDIVIDUAL, YET HIGHLY EFFICIENT

Our overall efficiency, even with enormously individual, tailor-made products, is achieved through our lean-optimized production area. The workflow is precisely specified by the production engineering group. Our well trained skilled employees watch every stage of production in terms of quality, precision and exactness of the product.

Furthermore, our workplaces are arranged according to the EH+S standard for environment, health and safety, so that we can provide security of our employees at all times during production.



QUALITY & REGULATORY

Quality Assurance and Regulatory Compliance

Strict and validated production processes for complete license compliance - even for highly individual requests: LRE's well established and comprehensive Quality Management System for medical devices, based on ISO 13485:2016 in alignment with 21 CFR 800 series and experience with relevant accreditations, provides our customers with a reliable and firm regulatory framework for product developing and full-scale manufacturing.

REALIZING CUSTOMER-SPECIFIC PRODUCTS COMPLIANT FOR MARKET INTRODUCTION

Our production processes, already starting with development over the procurement of regulation-fulfilling construction units up to the production itself, are always in such a way set up that they permit a barrier-free introduction of the product on the market. For this purpose LRE conducts close relationships with authorities, notified bodies and test houses for safety, so that our customers can easily obtain European and/or worldwide market approvals for their medical devices in line with directives and regulations such as MDD and IVDD for CE approval in Europe as well as for product release by FDA's or relevant authorities around the world.

In times of changing regulations with the newly coming European MDR and IFDR we actively support our customers over the next years by transitioning existing devices as well as developing new products in line with these new regulations.

QUALITY IS EVERYTHING

Quality assurance at LRE spans across all departments involved in product development and production. All activities mirror the fulfillment of quality requirements needed for safe, effective and innovative products for diagnostics, life sciences/analytics and medtech.



CASE SCENARIO

Six Days and running

We are grateful and proud to work with some of the best companies in the world. For over 60 years they trust us to create game changing innovation for them and to find the best solutions to their challenges. Take a look at one of our best projects!

We never cease to optimize our work and are always trying to come up with a better solution to our clients' problems. But sometimes it's all about timing. Especially during a pandemic crisis that has gripped the whole world.

Our task: Nothing less than scaling up manufacturing lines in record time – due to high demand of Molecular Diagnostics (MDx)

instruments for SARS-CoV-2 based on real-time polymerase chain reaction (PCR).

In only six days our experts in production engineering, production, logistics, supply chain and quality assurance not only came up with a concept and plan for this time-sensitive project. They also realized it with all the high quality and seamless precision LRE is known for.





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