



QualiMed®

Innovative Medizinprodukte GmbH





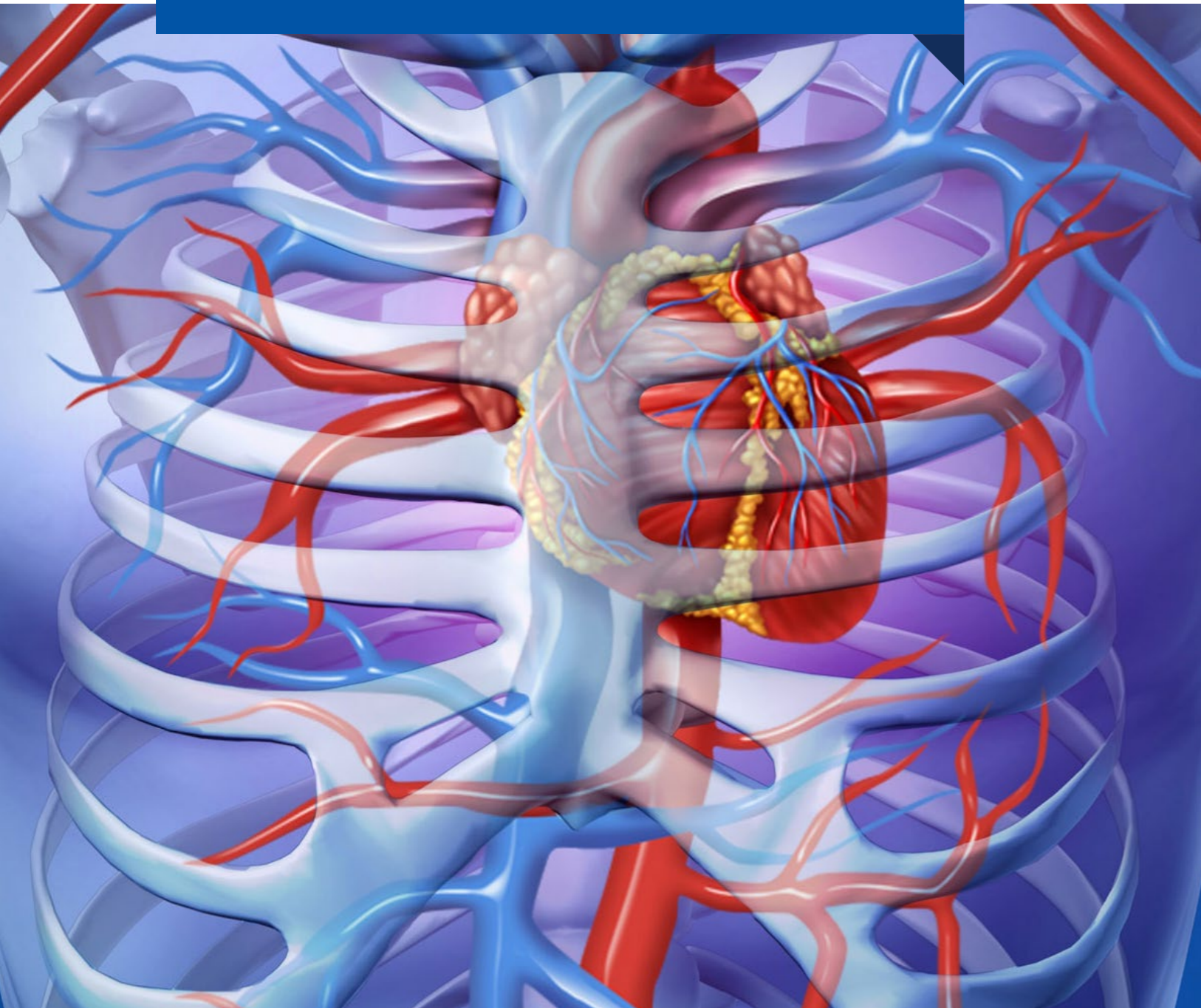
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As a leader in the development of innovative medical device technology to a large variety of interventional and surgical specialties doctors and the patients they treat globally, QualiMed is continually focused on enhancing its team of medical device professionals who are interested in working in the fast paced ever changing environment of medical device development.

The company is currently evaluating investment opportunities in various products, facilities, and strategic relationships that will enhance its long term strategic plans for growth in the mechanical, catheter, drug-device combination, and bioabsorbable technology areas.

**CE APPROVALS FOR MORE
THAN 70 DIFFERENT PRODUCTS**



COMPANY PROFILE

QualiMed was founded in 1997 by Martina Schmitt, Manfred Gülcher and Thomas Nissl as an OEM manufacturer for implantable medical devices with a focus on the development and regulatory approval of coronary stents and their respective delivery devices. Later the business was expanded to peripheral vascular and non vascular implants that included the world's first removable pulmonary, esophageal, and biliary stents. In the last two years QualiMed started with the development of various biodegradable technologies, drug device combination products, and orthopedic implants as part of its diversification strategy.

Up to date QualiMed has obtained CE approvals for more than 70 different products. QualiMed has developed over 5 Drug Eluting Stents of which it has three (3) CE approvals utilizing bio stable polymers and two more based on a proprietary fast absorbing biodegradable polymer coatings which (1) has obtained CE approval and is entering the commercialization phase. The company also has a number of the products with both CE & FDA approval and is the current sole source manufacturer of these technologies.

Manufacturing is organized in the plant outside of Hamburg Germany in the town of Winsen where QualiMed runs two Class 10,000 Clean rooms according to EEC GMP standards. The company has production capabilities for stents, catheters, drug device combination products, and biodegradable technologies for a variety of interventional and surgical applications and holds more than 70 patents and utility models World Wide.

In 2008 Eric K. Mangiardi joined the Board of Directors at QualiMed as an active investor with a primary focus to assist the company in the development and implementation of its strategic plan, operational growth, and product diversification strategy.



BOARD DIRECTORS

Martina Schmitt

Mrs. MARTINA SCHMITT is Managing Director and Partner at QualiMed and is responsible for the manufacturing plant and leads the Operational activities at QualiMed. Her focused expertise is in the areas of plastics and all catheter based projects in the company. Before QualiMed Mrs. Schmitt expertise was primarily in the installation and management of production facilities at Devon Medical Hamburg, Germany and the establishment and growth of an OEM-testing laboratory at EDAG AG. Previous to that she held executive positions in the automotive industry with a focus on materials technology.

Eric K. Mangiardi

ERIC K. MANGIARDI is currently the CEO of Q3 Medical Devices Limited. He joined the boards of Qualimed and AMG as an active investor with a focus on strategic planning, operational growth, product development, business development, and financial management. Mr. Mangiardi has held various senior positions in the Medical Device and IT industries, including President & CEO, Alveolus, Inc., Director of Corporate Strategy/Business Development (Healthcare), Atlas Commerce, and Regional Director, United States Surgical Corporation. He holds an MSc in International Marketing from the University of Strathclyde, Glasgow, Scotland and BSc. in Finance & Marketing from the University of Dayton, USA.

Manfred Guelcher

MANFRED GUELCHER is currently the Chief Risk Officer at Q3 Medical Devices Limited. Former he was a founder at Qualimed GmbH and Co-Managing Director with responsibilities for regulatory, quality, drug device combination technologies as well as EU funded R&D cooperation projects and some of Qualimed developments of innovative strategies in cardiac treatment like myocardial regeneration by retro infusion and Nanopore elution projects. Previous to founding Qualimed, Mr. Guelcher worked as manager for quality and regulatory affairs at Devon Medical, Hamburg, Germany, and as an auditor for medical devices at DEKRA (notified body), Stuttgart, Germany.

**FDA & CE
APPROVED**

QualiMed has obtained
FDA & CE approvals for more
than 70 different products

QualiMed is
the holder of over
75
patents
and utility models
worldwide

MODIFIED GENERIC STRATEGY

The Company has implemented its Modified Generic Sales Strategy ("MGS") that embraces a network computing based approach to commercialization where the channel is strengthened by its number of participants whom provide direct contact to the end customer through their long lasting established relationships. The Modified Generic Strategy Model allows the company to leverage these relationships through a variety of offerings via its OEM, Private Label, Own Brand, and Development channels. This expanded channel or "Network" approach allows Qualimed to leverage its core expertise and skills in design, development, and manufacturing while taking advantage of market consolidation conditions that have left many channel participants with a reduced portfolio of interventional products to sell seeking new innovative or comparable technology. Because these channel partners are well trained, have strong historical relationships with the key user base, and are working with physicians that are skilled in the clinical use of the technology, there is a significant opportunity to accelerate the company's growth through this multi-channel approach.

Relationship selling plays a significant role in what the doctors choose in the care for their patients and Qualimed plans to leverage this opportunity with its growing technology platform of innovative technologies.

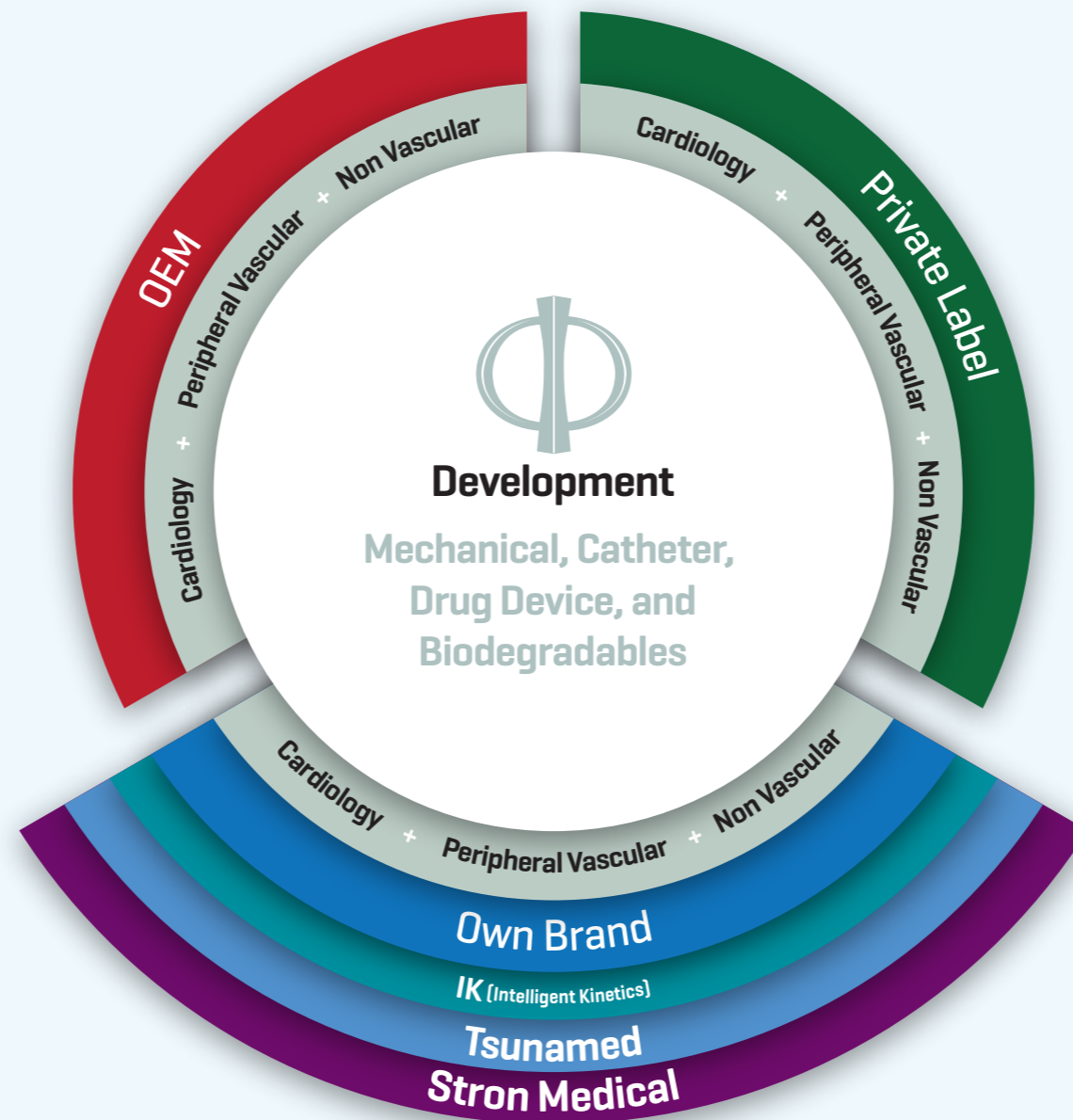
The company has chosen a targeted approach to reach the market through its expanding customer base broken out as follows:

1. Own Brand: The company's Own Brand lines offer a full range of products through a growing number of exclusive and non-exclusive distributors in Europe, Asia, the Middle East and Latin America. Currently the company is selling products or registering its technology in over 60 countries globally.

2. Private Label: The company provides a turnkey medical device offering to Private Label customers on a fee-for-service basis, which includes an upfront licensing fee for approved products in the coronary, peripheral vascular, and non-vascular areas. As part of the fee the company provides additional support services to accelerate the product transfers such as the establishment of a quality system for new entrants moving from pure distribution into having their own brand, CE transfers, inventory management, authorized representations, and other services as needed from time to time as requested by the customers. This private or 'white' label approach allows Qualimed to provide its products to multiple customers, further expanding its footprint in this highly fragmented market.

3. OEM: The company's OEM division produces products for its customers on an exclusive basis. These customers either bring existing products for production or desire new products to be designed, developed and manufactured at Qualimed. Qualimed only engages in paid or funded development projects where it will have control of the manufacturing rights in the future and can leverage the developments into some future application it will develop on its own.

4. Development: The company's Development is focused on novel development projects in the areas of Mechanical Implants, Catheters, Drug Device Combination, and Biodegradable technologies both internally sponsored by the company and its physician advisory network as well as externally funded projects from various corporate partners and government funded entities. Qualimed only engages in paid or funded development projects where it will have control of the manufacturing rights for completed developments and where developments will enhance the company's internal capabilities.



UNIQUE TECHNOLOGY

Biodegradables

- > Archimedes Biodegradable Biliary Stent
- > Pulmonary and Esophageal Fully Covered & Fully Bioabsorbable Stent
- > Perforation Management Device with Biodegradable Covering
- > Peripheral Vascular Balloon Expandable Biodegradable Stent
- > Coronary Biodegradable Magnatizable Stent

Cardiology

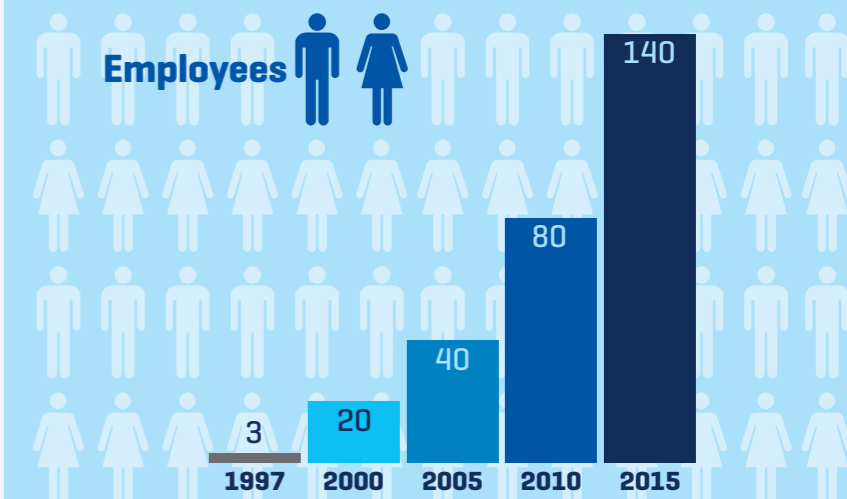
- > DES Sirolimus Drug & Fast Absorbing Polymer
- > Illuminating Balloons Eliminating Need for Contrast Media
- > CTO Device for Chronic Total Occlusions
- > Grow Stent for Infant Aortic Coartations
- > Complete line of Aspiration Devices including one of the World's Smallest Coronary System for Radial access and for difficult to reach extractions

Peripheral Vascular

- > Worlds 1st Bi-Directional Stent for SFA Applications
- > Line of PTA Balloons up to 300 mm in length
- > Illuminating Balloons Eliminating Need for Contrast Media
- > Sclerotic Balloon for vascular insufficiency
- > Fully Covered Stent for Peripheral Vascular Applications

Non Vascular

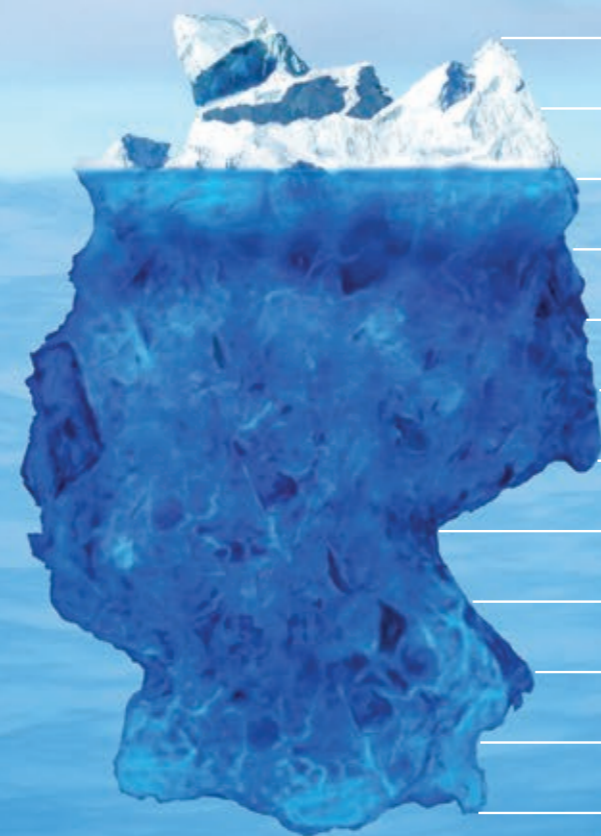
- > Fully Covered Removable Biliary Stent
- > Illuminating Balloons Eliminating Need for Contrast Media
- > Fully Covered Removable Esophageal Stent



DEVELOPMENT METHODOLOGY

The company is a Design, Development and Manufacturing firm specializing in medical device implants with a primary focus on implantable mechanical devices, catheter based technologies, drug device combination products, and biodegradable and bioabsorbable technologies. The company has vast expertise in taking products from any point in the development process from Ideation through manufacturing.

The company has created a 12 Step process to take products from Ideation through to manufacturing. The approach lets the companies team assess new ideas, market conditions, competitive landscapes, and current technology including IP in an effort to determine the viability of various technologies and partners it would choose to bring products to the manufacturing or continuous improvement phase of their life cycle.



OUR 12 STEP DEVELOPMENT GUARANTEE

- 12 ▲ Manufacturing
- 11 ▲ Clinical Testing
- 10 ▲ Animal Testing
- 9 ▲ Bench Testing
- 8 ▲ Prototype
- 7 ▲ Design Output Specification
- 6 ▲ Risk Analysis
- 5 ▲ Regulatory Assessment
- 4 ▲ Design Input Specification
- 3 ▲ Feasibility
- 2 ▲ Literature Review
- 1 ▲ Idea

The process based pathway methodology allows the company and its partners to evaluate opportunities from the ideation of a potential product through to commercialization with a focus on consistent risk mitigation throughout the development lifecycle regardless of the stage of development or commercialization. This unique method based approach to evaluate and manage a potential opportunity at any point in the products lifecycle of development uniquely positions the company to assist its customer partners to achieve their desired success.

The company's methodology is designed to achieve success through the early recognition of critical to quality parameters in the products development lifecycle that can cause increased risk to the pathway leading to the commercialization of the technology and continuous product improvements thereafter.

BUSINESS UNITS

- OEM
- Private Label
- Own Brand
- Development

CLINICAL FOCUS

- Cardiology
- Peripheral Vascular
- Non Vascular
- Others

PRODUCT MIX

- Mechanical Implants
- Catheter based Technologies
- Drug Device combinations
- Biodegradables

OUR 12 STEPS

PHASE 1 IDEATION

The company's Research and Development Department assists customers with taking their ideas from thoughts to clinical implants through what we call conceptual development. During the Ideation Phase the company documents the initial concept or idea that needs to be explored in detail.

PHASE 2 LITERATURE REVIEW

During the initial design phase and throughout the product lifecycle the company utilizes an extensive literature review process to consistently and accurately assess existing product outcomes and modalities to insure proper user needs identification based on key critical to quality parameters outlined based on complication rates and success rates established in the historical literature.

PHASE 3 FEASIBILITY

During the feasibility phase the company along with its partners assess the real market opportunity for the technologies success based on a number of critical elements the company has established to insure that the company and its partners achieve their respective levels of success.

PHASE 4 DESIGN INPUT SPECIFICATION

The company uses the Design Input Specification phase of its development methodology as a risk mitigation tool to assess the required design inputs to achieve the appropriate design outputs based on key user needs specifications that are then validated by the literature review, feasibility assessment, and expert user input to insure the greatest opportunity for meeting the requirements of the initial Idea.

PHASE 5 REGULATORY ASSESSMENT

During the regulatory assessment phase the company utilizes its extensive staff of regulatory personnel to evaluate the global regulatory needs to launch the devices commercially while linking these commercialization requirements to the specific testing that will be utilized during development up to the initial regulatory approval.

PHASE 6 RISK ANALYSIS

The risk analysis phase is used to accurately reflect and document the product risk for each of the parameters to insure that all the participants are focused on what the company terms its Tri-Level risk mitigation methodology to minimize any external risk that could jeopardize the development or time lines.

PHASE 7 DESIGN OUTPUT SPECIFICATION

During the Design Output Specification Phase the company establishes and maintains procedures for defining and documenting design output in terms that allow an adequate evaluation of conformance to design input requirements. The Design output procedures shall contain or make reference to acceptance criteria and shall ensure that those design outputs that are essential for the proper functioning of the device are identified. The Design output is documented, reviewed, and approved before release while the approval, including the date and signature of the individual(s) approving the output, are documented.

PHASE 8 PROTOTYPE

The company utilizes a three stage prototyping process to insure that the user needs specification are achieved in the design output specifications.

PHASE 9 BENCH TESTING REQUIREMENTS

Bench testing is an essential element to insure that the user needs specifications are met as defined in the design input and output specifications. The bench testing is established to accurately assess whether the design meets the user needs requirements.

PHASE 10 ANIMAL TESTING

The company uses the animal trial phase of the development process to further validate that the user needs specifications are met through the design inputs and validated in the design outputs. The company has the capabilities to manage the animal trial process from the protocol writing to testing of the technology through various partner facilities throughout the world.

PHASE 11 CLINICAL TESTING & REGULATORY APPROVAL

The company will assist its partners in validating the designs through rigorous clinical testing of the technology and can assist or run the clinical studies as desired by its partners with a focus on generating the data required to achieve regulatory approval for the technology globally.

PHASE 12 MANUFACTURING

The company has established a manufacturing skill set to produce high quality implantable technology and catheter based applications through its ISO 13485:2003 and ISO 9001:2008 certified facility and through its global manufacturing partner relationship in Asia, Europe, and North America.



MANUFACTURING & DEVELOPMENT

The company is a full service provider of implantable interventional and surgical devices, catheters, drug device combination products and biodegradable implants all produced at its manufacturing facility based outside of Hamburg German. The company will only engage in development projects where it has committed manufacturing volumes for the global market once the devices pass through the regulatory stage of development.

The company is known worldwide as a leading designer, developer, producer, and seller of implantable devices. The company has extensive expertise with mechanical devices used in all interventional and surgical areas as well as various catheter technologies including ballooning with various materials, sizes, and diameters. Additionally, the company has developed a number of drug device combination products that are currently being sold worldwide through its sales channel.

Biodegradable

The company focuses on individual solutions for its partner customers that address the special requirements of the application in the human body. The company has current biodegradable expertise and offers different material solutions like magnesium, iron, biodegradable polymers, and hydrogel for the construction of medical device implants. The degradation time can be varied from weeks to years in the human body depending on the anatomical requirements where the devices are implanted. The company is currently working on additional combination materials to enhance future applications and use.

The company has a steadfast belief that Biodegradable implants will offer a new way of healing for future generations' worldwide.

Mechanical

The company develops and manufactures a variety of different technologies for medical device implants ranging from small coronary or neuro implants to large bore stent for pulmonary, esophageal, and other gastro intestinal indications. The company has the ability to perform all steps of the production process for the early design and prototyping through to scale up and production.

Catheter

The company has the capabilities to deliver various single and multi lumen catheters made from a large selection of materials specifically selected based on our customers design input specifications including but not

limited to strong platform materials like polyamides and polyamide blends, PEEK, Polyimide, braided tubes and various multilayer tubing's.

Balloon

The company has balloon blowing expertise to get high quality balloons with different customized behavior like non-compliant, semi-compliant and compliant balloons. The company has capabilities to use different materials and one or more multi-layer tubing's to build the balloons, this coupled with a modern, complete process controlled manufacturing process, allows for the production of virtually any design with a controlled constant balloon behavior.

Drug Device Combination

The company has capabilities to coat materials with bio stable and biodegradable polymers such as stainless steel, cobalt chromium, nitinol, other alloys, nylons, urethanes, and an assortment of other materials with a variety of drugs including paclitaxel and sirolimus based pharmacologics.

Regulatory requirements for Drug Combination Devices are much more complicated because medical device regulations as well as medicinal substance regulations are involved. The company can assist in helping its customer partners establish their regulatory strategies involving drug device combination technologies.

Coatings & Coverings

The company developed and established different technologies for coatings and coverings of medical products in the broadest sense. This includes ion implantation technology to improve surface biocompatibility, covered stents to prevent in growth, and coated surfaces as a material to create a base to launch drugs elution properties from. The company has coating capabilities for dip coating, spray coating, an electro spinning.

Regulatory

Regulatory strategies and assessments are involved in an early stage of the QualiMed development methodology. After the product or concept Idea Phase is initiated a corresponding literature review and feasibility assessment will be performed and supported by the Regulatory Affairs department to make sure that ideas will have a certain level of approval success at the end of the development and the commencement of commercialization.

Clinical Expertise

Over the past ten years the company has established clinical trial channel to test products and technologies in the areas of interventional cardiology, peripheral vascular, and non-vascular areas. The company is utilizing its network of clinical advisors to insure that the right groups are established to execute on the clinical

testing needs for its technology and to produce clinical papers to support its developments and subsequent launch of its technology.

Once products are approved this network can be used to help with the clinical introduction of the technology as well as aftermarket training as needed.

Clinical Areas of Expertise

The company has an extensive network and expertise in various clinical specialties and is focused on leveraging these relationships to insure that products meet the clinical needs in the market. Once products are approved this network can be used to help with the clinical introduction of the technology into the market.

Quality

The company is running a modern Quality Management System focusing on controlling processes and building in quality from the early product stages. The company is certified to ISO 13485:2003 and ISO 9001:2008 standards and Medical Device Directive 93/42 Annex II and V.

Risk management throughout the development process is the company's key tool to achieve safe product design, selection of best components, and to implement the right controls in production.

FACILITIES

Manufacturing is organized in a plant in the south of Hamburg in Winsen, Germany where the company owns an area of more than 16,000 m². The plant area of 3.000 m² includes a variety of different possibilities regarding manufacturing conditions.

The company runs two ISO Class 7 clean rooms.

The core production technologies for in-house processes include, but are not limited, to the following:

- > **Laser-cutting**
- > **Heat treatment**
- > **Electro-polishing** (e.g. stainless steel, Cobalt Chromium based metals, Nickel Titanium alloys)
- > **Ion Implantation for surface refinement** (e.g. Carbon, Oxygen, Nitrogen, CO)
- > **Forming process of shape memory alloys** (e.g. Nickel Titanium)
- > **Crimping process** (digital pressure controlled crimping)
- > **Covering and Coatings** (e.g. PU, Silicone, ePTFE, hydrophilic, mesh, electrospun, dip, spray, and others as needed)
- > **Drug coating** (e.g. biostable polymer based, biodegradable polymer based, polymer-free based)
- > **Catheter manufacturing** (e.g. PTCA, PTA, Stent Delivery balloon expandable and self-expandable, Aspiration, CTO)
- > **Gene technology** (e.g. siRNA coating on stents)
- > **Biodegradable polymers and alloys for stents, staples, and other implants** (e.g. coronary, peripheral and biliary stents of different biodegradable polymers or absorbable metals)

All manufacturing processes are focused on customization which is not limited to the above mentioned technologies and processes with nearly all manufacturing and laboratory equipment including all testing and validation equipment was developed and built in-house.

CAPABILITIES

Regulatory

- > Strategy
- > Animal & clinical testing
- > Filing
- > Post market surveillance

Development

- > Biodegradables
- > Drug device combinations
- > Catheter and delivery devices
- > Mechanicals

Manufacturing

- > 2 class 10.000 Cleanroom
- > Implants catheters and balloons
- > Covering and coating
- > Biodegradables
- > Drug device combination technologies

Services

- > Testing
- > Distribution
- > Authorization / Representatives
- > Consulting

PRODUCTS



The company is offering a variety of products for OEM, Private Label and Own Brand in the areas of mechanical, catheter, drug device, and biodegradable based technologies. The company provides the devices fully assembled and available for shipment in bulk or we can provide the devices packaged and sterilized based on your unique container design and marketing requirements. Additionally we will provide component devices in the form of finished stents and catheters.

The company offers a full range of compliant and semi compliant balloons for coronary, peripheral vascular, and non vascular procedures including interventional urology, gastroenterology, and urologic procedures.

Stents have been the core business of the company since the inception of the company. The company has numerous patents related to various stent designs with IP protection in various countries throughout Europe, Asia, and the Americas. The company has extensive experience in a variety of materials such as surgical stainless steel (316LVM), Cobalt Chromium (L605), Nickel Titanium, Titanium, Tantalum, combination alloys, and is currently working on next generation materials for enhanced functionality and visualization. The company has the ability to leverage its own patented designs or generate new designs based on the specific needs of its customer partners.

MECHANICAL

- > Cobalt Chromium Stents
- > Stainless Steel Stents
- > Carbon Impregnated Stents
- > Nitinol Stents
- > Q3 Bi-Directional SFA Stent
- > Balloon Expandable Peripheral Stents
- > Carotid Stents (Straight & Conical)
- > Covered Stents
- > Biliary Stents
- > Tracheobronchial Stents
- > Esophageal Stents
- > Cricoid & Low Anterior Resection Stents
- > Grow Stent and Balloons
- > CoCr Magnitude
- > ATAG Aortic Aneurysm device

CATHETER

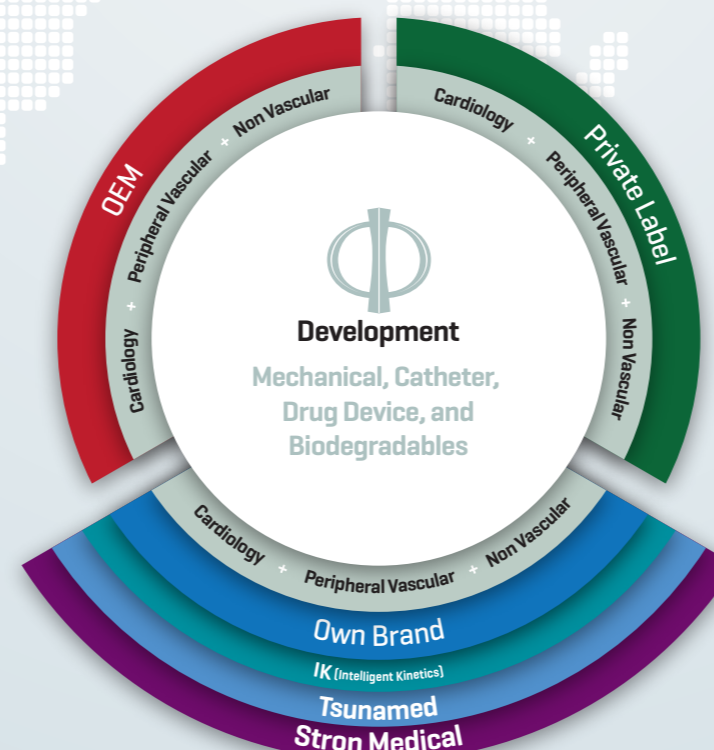
- > Aspiration Catheters (5F, 6F and 7F)
- > PTCA Catheters
- > PTA Catheters
- > Peripheral Vascular Catheters
- > PTCA Balloons
- > PTA Balloons
- > Non Vascular Balloons
- > PTCA Non Compliant Balloons
- > Sclerotic Balloons
- > Biliary Balloons
- > Dilating Balloons
- > Dilating Magnitude
- > PTA and PTCA Magnitude
- > Carotid Filter
- > AV Shunt

DRUG DEVICE

- > Stent Systems
- > Coronary Stent Systems (Stainless Steel, Cobalt Chromium, Drug Eluting)
- > Peripheral Vascular Stent Systems (Balloon Expandable & Self Expanding)
- > Drug Eluting Stent (DES)
 - a. Paclitaxel
 - b. Rapamycin
- > Drug Eluting Balloons
- > Drug Eluting Balloon in Balloon with Gel
- > DEB Magnitude

BIODEGRADABLES

- > Biliary Stents
- > Pulmonary Stents
- > Esophageal Stents
- > Perforation Management Device
- > Coronary





HISTORY AND MILESTONES



- 2015** > MARKET LEADER IN BIODEGRADABLE IMPLANTABLE DEVICES
 - > CORONARY BIODEGRADABLE STENT
 - > PERIPHERAL BIODEGRADABLE STENT
 - > NON VASCULAR BIODEGRADABLE IMPLANTS
 - > OTHERS INCLUDING: FIXATION > CLOSURE > STABILIZATION IN VARIOUS STAGES OF DEVELOPMENT
- 2014** > BALLOON EXPANDIBLE FULLY BIODEGRADABLE STENT (CLINICALS COMPLETED)
 - > DRUG DELIVERY (SCLEROTIC AGENT) FOR VENOUS INSUFFICIENCY (APPROVAL EXPECTED)
- 2013** > FIRST FULLY BIODEGRADABLE BILIARY STENT (APPROVAL EXPECTED)
 - > BIODEGRADABLE COVERED ESOPHAGEAL STENTS (CLINICALS COMPLETED)
- 2012** > CE APPROVAL FOR SIROLIMUS BIODEGRADABLE COATED STENT
 - > COMPLETION OF PERIPHERAL LINE
- 2011** > CE FOR PERIPHERAL SFA STENT
 - > ASPIRATION LINE
- 2010** > ESTABLISHING MODIFIED GENERIC STRATEGY
- 2009** > STARTING BIODEGRADABLE R&D WORK
- 2008** > ESTABLISHING CATHETER AND BALLOON MANUFACTURING AREA
- 2006** > CE APPROVAL FOR THREE PACLITAXEL DRUG ELUTING STENT
- 2001** > EXPANDING PRODUCTION AREA
- 2000** > ENTER INTO NON VASCULAR
- 1997** > FOUNDATION IN WINSEN / LUHE
 - > OEM MANUFACTURER FOR IMPLANTABLE MEDICAL DEVICES
 - > CORONARY APPLICATION

STAY IN TOUCH

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Product Development in Cardiology, Peripheral Vascular,
Non Vascular and Biodegradable