Extrusion
Molding
Assembly

RAUMEDIC

Your development partner and system supplier for the medical and pharmaceutical industry
RAUMEDIC – your development partner and system supplier for the medical and pharmaceutical industry.

We are a partner of the worldwide medical and pharmaceutical industry and a leading developer and manufacturer of polymer systems and components. In close collaboration with our customers, we contribute to the development of innovative diagnostic and acute therapy systems.

From the initial idea to serial production, we act as partner and consultant to our customers. With over 70 years of manufacturing expertise in the fields of extrusion, injection molding and assembly, we are ideally equipped to convert your requirements and concepts into mature medical products.

RAUMEDIC headquarters in Helmbrechts

Quality management

We understand the importance of quality, and give you our full support in complying with the regulations.

Customer satisfaction and compliance with all relevant statutory, normative and official requirements are the focus of our quality concept. RAUMEDIC has established a comprehensive and certified quality management system for our customers in order to satisfy the demanding requirements for the materials used in medical technology.

- Certified QM system according to ISO 13485
- Certified according to ISO 15378 (Primary packaging materials for medical products)
- Clean room production according to ISO 14644, Class 7 (=10,000)
- Manufacturing according to GMP standards
- CE approvals for RAUMEDIC medical devices

This means that we ensure compliance with the most important standards and guarantee your complete satisfaction from the design to the finished product.
RAUMEDIC continually researches new materials, formulations and products, so that we can always ensure the well-being of patients and optimal materials for physicians. Our research and development activities benefit from the many years of experience of our own laboratory staff.

Our engineers will be happy to advise you on design, the selection of materials and production of the first prototypes, through to the finished product and manufacturing concept.

Thanks to modern production equipment and precision work “Made in Germany and the USA”, we meet the highest standards of quality and safety.

Individual products require different approaches

RAUMEDIC achieves the best possible functionality with intuitive and ergonomic operation according to the customer’s requirements. We attach great importance to production-oriented design and cost-effective manufacturing processes.

We stay in close touch with you all the way from the initial concept through to the finished product. In order to make product development as efficient as possible for our customers, we construct prototypes. This helps us to provide fast and economical solutions for the production of samples and batches.
Material expertise

You know the requirements on your product – we know the appropriate material.

Material research and development have been one of RAUMEDIC’s core competencies for over 70 years. By working closely with leading research institutions, we are steadily expanding our material-specific expertise in the fields of thermoplastic and silicone materials. RAUMEDIC processes all thermoplastic polymers and silicones at medical quality.

Material formulation

Customized material formulations for processing in extrusion and injection molding.

We help you to choose the right material for your product on the basis of this expertise. Of course, we always take interactions with media such as blood or infusion solutions into account. Aspects of further processing and assembly are also involved in the selection of materials.

By setting high standards, RAUMEDIC ensures consistent quality from the selection of raw materials and compounding through to the final product. And we leave nothing to chance. All production processes are carried out in a closed material flow with qualified equipment. Preparation and processing take place under conditions that cause extremely low levels of material wear and tear.

Customized PVC formulations

- Specific sterilization methods
- Good resilience for pump applications
- Customized shore hardness and color
- Suitable for contrast X-rays
- Adapted to all available plasticizers
- Only tested raw materials
PVC raw materials and plasticizers

We provide comprehensive and competent consulting in the selection of raw materials and the right plasticizer for your products.

The quality of a medical product begins with its raw materials

The quality and suitability of a product depend, to a large extent, on the quality of its ingredients. For this reason, we only use raw materials with tested chemical, biological and toxicological properties for our formulations.

Through decades of experience in the field of formulating and preparing soft PVC, we have succeeded in setting new standards for the preparation of our own compounds. The phthalate-free plasticizer, noDOP®, which has since become established worldwide, is just one example. It is characterized by extremely low migration and excellent biocompatibility.

Choice of the ideal plasticizer

Choosing the right plasticizer for your application lays the foundation for the product and its suitability for practical application. We would be happy to help you with our expertise in the use of the following plasticizers:

- noDOP® (TEHTM)
- DEHT
- Di-Isododecyl-CycloHexane-1,2-dicarboxylate
- ATBC
- DEHP

Please visit our website for more information.

Correct processing is the basis for a customized PVC solution

Within the context of compounding, our raw materials are processed on dedicated production lines without contact with the environment, in a process that minimizes wear and tear on the materials. This makes it possible for us to manufacture proprietary compounds that are tailor-made for medical applications.

- Processing in accordance with current state-of-the-art process engineering
- Ensuring quality by means of validated, fully automated process control
- Lot-based quality testing
- Purity ensured by closed material flow from raw material delivery to the finished product
- Several processing systems at two sites ensure supply security, punctuality and customer-oriented flexibility

Pure-grade compounds – an important step towards a safe PVC product.

From compounding to a comprehensive PVC solution

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 Tested, documented quality and certified quality system for more product safety

It takes a great deal of experience, know-how and technical ability to develop a high-quality medical device from the drawing board to completion. As a leading provider of medical plastic products, we develop reliable and customized complete PVC solutions in close cooperation with our customers.

Each of our products undergoes a variety of external and internal tests in order to satisfy our responsibility to the patients. This allows us to ensure the highest level of safety for our raw materials and products. Of course, quality is constantly monitored, documented and confirmed throughout the production process, with test certificates for each batch.
Fluoropolymers

Fluoropolymers are used when the product must possess special sliding properties.

Fluoropolymers, such as PFA, FEP, and PTFE, are very resistant to almost all chemical compounds and solvents. Their outstanding features are very low slippage and excellent biocompatibility.

Depending on the intended application, we match the material optimally to your requirements. We also produce spools and cut lengths to the dimensions you specify. In addition, we can incorporate X-ray contrast stripes – variable in number and shape – or offer full contrast tubing.

With good coating and lubricating properties, fluoropolymers are also ideal for wire coating, e.g. for our VariCoat® product range.

**Thermoplastic PTFE**

Thermoplastic PTFE is a special fluoropolymer. It provides the perfect combination of PTFE material characteristics and thermoplastic processability.

RAUMEDIC has expanded its material expertise to include this unique material. This opens up completely new possibilities for a wide range of medical devices, both for you as a customer and for us as a manufacturer.

- Nearly universal chemical resistance
- Very good sliding properties
- Capacity for further thermoplastic processing
- High temperature resistance

Unlike conventional PTFE, thermoplastic PTFE can be formed and flared without stress cracking or flaking.

Silicone expertise

Scarcely any other material is as versatile in its use or offers such a wide range of beneficial properties.

Silicone is an excellent material for medical applications. Due to its elastomeric nature, it offers unique properties that cannot be achieved with thermoplastic materials.

**Advantages of silicone**

- Constant material properties within a wide temperature range from -70 °C (-94 °F) to 250 °C (482 °F)
- Excellent pump performance
- High degree of biocompatibility
- Particularly low extractable profile
- All common sterilization methods are possible

**Possible areas of application**

- Pharma Fluid Handling
- ECC
- Infusion and nutrition
- Drainage
- Pharmaceutical packaging
Our range of materials for tubing extrusion includes all common thermoplastics and elastomers.

**Smallest dimensions for RAUMEDIC extruded tubing**

Our products can be adjusted to accommodate the respective requirements.

- Internal diameters starting at 0.002" (0.05 mm)
- Wall thicknesses starting at 0.002" (0.05 mm)
- Micro layers with thicknesses starting at 0.0002" (0.005 mm), can be combined up to four layers
- All common thermoplastics up to high-performance plastics can be selected

**Thin walled PUR tubing**

The wall thickness of thin walled tubing is comparable to the thickness of a human hair. The tubing is therefore very suitable for balloon applications and is used for endotracheal intubation to secure the airways in the areas of anesthesia and emergency medicine.

- Internal diameters from 0.079" (2 mm) to 0.394" (10 mm)
- Wall thicknesses from 0.002" (0.05 mm) to 0.006" (0.15 mm)
- Surface from high-gloss to micro-rough

**Multilumen tubing**

Multilumen tubing can be configured according to the customer's requirements, and can therefore be used in a wide variety of applications.

The material and cross-sectional patterns are tailored to your requirements. This has the following advantages for your application:

- Achieving maximum flow rates
- Delivery of medications via different channels for diagnostic investigations

Typical products are catheters and endoscopes in areas such as:

- Nutrition
- Drainage
- Urology
- Dialysis
Multilayer tubing

Multilayer tubing is used when the properties of a single material do not allow us to generate the special characteristics of a product.

Multilayer tubing provides modern, effective and practical solutions for wide-ranging medical applications. Especially in cases when standards and production technology of a medical system require the use of several materials. For example, this is the case if the inside and outside of the tubing must have different properties.

Minimally invasive surgery requires increasingly complex catheters to ensure the patient’s well-being during treatment. Even in diagnostics, miniature tubing are used more and more frequently due to sample quantities becoming continually smaller. Up to four different materials can be combined in our multilayer tubing. The smallest inner diameter ever achieved is approximately 0.012” (0.3 mm).

Combination of up to three specially formulated polymer compounds allows targeted adjustment of manual or automated manufacturing processes for optimal further processing in your production facility.

Filling tubing for welding into film bags

Filling tubing from RAUMEDIC is used, for example, as connector tubing for infusion and dialysis bag applications.

- Secure adhesion of press-fit connectors made of various materials such as PC and ABS
- Optimal weldability using all common types of films
- Processable on different types of machines
- No delamination of individual layers
- No bonding of connectors required due to their secure hold after steam sterilization

2 Materials

3 Materials

4 Materials

Application: Insulin treatment

Application: Percutaneous transluminal coronary angioplasty (PTCA)

Application: Regional anesthesia

2-layer tubing

3-layer tubing

2-layer tubing

3-layer tubing

4-layer tubing

5-layer tubing
RAUSORB
Light-sensitive pharmaceuticals that are destroyed by photochemical reactions play an increasingly important role in therapy. Coloring the outer layer produces a filter that absorbs the harmful wavelengths of light.

RAUINERT
Low dosage rates of modern medications result in higher dwell times in the tubing system. RAUINERT tubing minimizes the risk of unwanted interactions between the drugs and tubing.

RAUSONERT
Low-dose, light-sensitive preparations place high demands on the transport tubing. RAUSONERT combines all advantages of RAUSORB and RAUINERT in one tubing.

The RAUMEDIC product portfolio offers two versions designed especially for high pressure applications – reinforced high pressure tubing and coextruded high pressure tubing. For both versions, we use exclusively LAL-compliant raw materials. A coreless extrusion process in a class 7 clean room environment results in freedom from particulates as defined in the USP 788 standard.

Reinforced high pressure tubing
- Outstanding flexibility and optimal kink resistance
- Adjustable transparency
- High pressure resistance (> 83 bar / 1,200 psi)

Make-up: Spools and fixed lengths

Coextruded high pressure tubing
- Flexibility can be adapted to customer specifications
- Good transparency due to the non-reinforced design
- High pressure resistance (> 83 bar / 1,200 psi)

Make-up: Fixed lengths
Coated micro cables and wire inlays

RAUMEDIC is your skilled development partner for coated micro cables and wire inlays based on customer requirements. With thermoplastic extrusion, we can combine variable support materials, such as wires, braids and synthetic fibers, with a wide variety of polymers. We also process high-temperature thermoplastics such as PFA, FEP, PEEK and thermoplastic PTFE. We attach great importance to the individual needs of our customers.

Coated micro cables and wires

- Customized wire materials such as 304V and nitinol
- Selection of a polymer suited to your requirements
- Layer thicknesses starting at 0.0008" (0.02 mm)
- Wire diameters from 0.002" (0.05 mm) to 0.039" (1 mm)

Wire inlay

- Customized wire materials are possible
- Selection of a polymer suited to your requirements
- Wall thicknesses starting at 0.024" (0.6 mm) and inner diameter 0.059" (1.5 mm)
- Wire diameters from 0.002" (0.2 mm) to 0.039" (1 mm)

Intravenous catheters

As a system supplier, in addition to catheter tubing, RAUMEDIC also has the production know-how for almost all plastic components needed for peripheral intravenous catheters.

Examples of RAUMEDIC extrusion expertise include peripheral intravenous catheters, which are available as spools or in fixed lengths. Thermoplastic PTFE, FEP and PUR are the materials used.

We can provide the following components of a peripheral intravenous catheter for you:

- Cannula protection as an extruded tubing or injection molded cap
- Butterfly
- Tubing for silicone valve sealing
- Intravenous cannula

Your benefits at a glance

- Good processability when forming the tip and flaring the cannula end
- Excellent blood- and biocompatibility
- Quality tests according to customer requirements

Intravenous cannula for drug administration
Naturally non-PVC materials are explicitly used in manufacturing our lay flat tubing. As such, these materials are very well suited for use as pharmaceutical packaging.

These characteristics make RAUMEDIC lay flat tubing the optimal solution for enteral and parenteral nutrition, as well as for cryopreservation:

- Excellent process capability on high-speed assembly lines
- Flexible film widths from 3.94” (100 mm) to 19.69” (500 mm)
- Variable wall thicknesses from 0.004” (0.1 mm) to 0.016” (0.4 mm)
- Inner surface options include a textured design, longitudinal ribbing or a smooth surface
- Very good transparency due to a special manufacturing process
- Specific transmission characteristics possible through film coloration

**Micro lay flat tubing**

The micro lay flat tubing manufactured by RAUMEDIC in the clean room is used, for instance, in medical engineering as protective tubing.

- Flat width max. 0.984” (25 mm)
- Wall thickness starting at 0.002” (0.05 mm)
- Material: Polyethylene

**Gas supply tubing**

Optimal equipment for your artificial respiration, anesthesia and emergency devices with RAUMEDIC tubing for medical gas supply.

RAUMEDIC tubing for medical gas supply in the Shore 87A hardness setting corresponds in terms of tubing relevant aspects to DIN EN ISO 5359 (low pressure tubing assemblies for use with medical gases). The formulations used are physiologically harmless and are adapted for the gases such as nitrous oxide, nitrogen, compressed air, oxygen or carbon dioxide.

- Burst pressure up to 70 bar (1,015 psi)
- Adhesive force of the tubing layers min. 1.5 kN/m
- Electrical resistance 3 x 10³ to 3 x 10⁶ Ω/m (for types modified to be electrically conductive)

Our gas supply tubing consists of an inner tube, polymer filament reinforcement and the sheath. Special formulations as well as anti-static (electrically conductive) versions are possible at the customer’s request.
Silicone tubing

RAUMEDIC silicone is the proven tubing for the use in pharmaceuticals and medicine.

RAUMEDIC silicone tubing is made of highly resistant, high-quality silicone, which is exceptionally suited for the use in pharmaceutical and medical engineering. Thanks to our years of expertise in production, our silicone tubing has a particularly low extractable content. This ensures outstanding biocompatibility. For selected materials, we can also provide you with comprehensive validation documents for rapid and straightforward customer-specific implementation.

Product portfolio

- Silicone, platinum or peroxide cross-linked
- Shore hardness A 30-80
- Reinforced for high pressure applications
- Full contrast or with X-ray contrast stripes
- Individual printing is possible

Patented surface treatment

- Low-Tack
  Reduced tackiness of the surface
- Antimicrobial surfaces
  Protection against a variety of clinical germs

RAUMEDIC adhesive and dispersion – safety and protection for your medical devices.

EXTRUSION

Extra-Corporeal-Circulation (ECC)

Our ECC products have proven themselves for over 60 years in many countries. As a medical device they are provided with CE marking. An extensive range in stock enables rapid and reliable delivery.

ECC tubing made of noDOP®

RAUMEDIC-ECC-noDOP® tubing is free of DEHP and has a particularly smooth inner surface, which provides outstanding blood compatibility (comparable to that of polyurethane). As a DOP-free material, it is not subject to the labeling requirement for phthalates.

ECC connectors

RAUMEDIC ECC connectors are compact in design in order to minimize the surface area exposed to the patient’s blood. They are made of polycarbonate as a single casting and meet the highest mechanical requirements.

ECC silicone tubing

Maximum reliability and safety as well as tight tolerances are vital, particularly with the ECC roller pump. Our RAUMEDIC ECC pump tubing has set standards in medical technology for many years. Its high transparency and optical quality ensure that bubbles in the blood are detected in good time. ECC silicone tubing is always printed to avoid confusion and document its high quality.
Our strengths include customized design and manufacture, from complex parts and assemblies through to complete systems.

We manufacture high-precision injection molded parts with part weights from 1 g to 200 g under clean room conditions. Our manufacturing processes have been validated and are guaranteed through application of appropriate statistical methods.

We process all thermoplastic polymers up to and including high temperature thermoplastics as well as silicone. A team of specialized engineers and technicians is at your side from the initial idea to series production. Our services include the development and production of molded parts and the assembly of complex groups of components, including customized packaging and sterilization.

The miniaturization of molded parts and complete groups of components is becoming increasingly important in the medical and pharmaceutical sectors.

In order to meet high customer and quality standards, all phases and processes must be specially designed for micro injection molding.

With micro injection molding, we produce product parts with weights of 0.004 g to 1 g. A wide range of thermoplastics and high-temperature thermoplastics is also used, such as PEEK, PSU and silicones.

Complete groups of components and systems from one source

- Micro injection molding
- Micro extrusion
- Micro assembly

PEEK tubing with overmolded tip for stent catheter

Application system for liquid drugs

Customized dental application in sterile packaging
Multi-component injection molding

With multi-component technology, various product characteristics can be combined with cost-effective manufacturing options.

Insert molding and overmolding

In the cases of insert molding and overmolding, we bundle our expertise in extrusion and injection molding into a single group of components. Even materials that cannot be glued can be successfully joined together with insert molding and overmolding. Furthermore, high tensile loads and pressure tightness can be achieved with injection molding of parts onto metal and plastic cannulas.

The advantages of this process

- Manual, semi- and fully automated handling of insert parts during the injection molding process
- Optimal bond between the individual components
- Strict requirements on leak tightness

Multi-component injection molding allows us to combine and process a large number of polymers. With this technology, we can implement innovative ideas for products in the areas of medical technology and pharmaceuticals.

Sandwich injection molding

Multi-component injection molding makes it possible to integrate additional functionality into individual components. In sandwich injection molding, the use of two materials with different barrier properties makes it possible to reduce both water vapor and oxygen permeation.

Combining hard and soft components to make one single component

The combination of a hard thermoplastic component with a soft elastic component opens up new perspectives in medical technology, such as sealing elements or pharmaceutical dosing systems.

Drug container with barrier function

Catheter coupling for regional anesthesia

Insert molding and overmolding of molded parts – the alternative to gluing.

Luer cannula for eye surgery

Overmoulded connector on a PVC tubing for inhaler applications
Disposable patch pump for the treatment of heart failure

Different injection and safety systems

Primary packaging for liquid drugs

Silicone injection molding at RAUMEDIC – true added value. Combine your ideas with our passion for silicone.

Components and systems for the pharmaceutical industry

Together with our customers, we have specialized in the field of pharmaceuticals in the following product groups.

We are specialists in the processing of liquid (LSR/LIM) and high consistency silicone rubber (HCR/HTV). Even 2-component applications in the silicone/silicone or silicone/thermoplastic variants are included in our repertoire.

With our many years of experience in medical technology, we support you along the entire value chain of your product.

Competencies

- Sophisticated product and tool design
- Optimal material formulation for your application
- Customized tool technology for your medical and pharmaceutical products
- Qualified and validated processes for maximum process reliability

Possible areas of application

- Pump segments for food and drug pumps
- Silicone plugs for syringe systems
- Insert molded connectors for feeding tubing and catheters
- Seals for the medical and pharmaceutical industry
- Thin-walled molded parts for inhalation systems

Drug delivery systems

Drugs can be fully effective only when their doses are correct. Using our customized solutions, we ensure that drugs are properly dosed.

Injection systems

We develop intelligent injection systems together with you. In this way, we can ensure the quality and safety of your medications.

Primary and secondary packaging

Due to our wide range of manufacturing methods we are able to find innovative and customized packaging solutions for your drugs. Thus, your active pharmaceutical ingredient is optimally packaged.
Catheter assembly

Our wide range of manufactured items allows us to combine tubing and components into customer-specific, CE-certified and sterile-packaged systems.

Different manufacturing options at RAUMEDIC
- Punching
- Printing (including high-temperature materials)
- Tip forming
- Thermoforming
- Microchip technology
- Integration of electronic components
- Packaging
- Sterilization
- Certification

Manufacturing technologies
- Micro extrusion of multilumen tubing
- Precision injection molding of the connector
- Overall assembly of delicate components into the final product

Tubing sets

Tubing sets assembled by RAUMEDIC are used, among other purposes, in the areas of ophthalmology, radiology, dialysis and arthroscopy.

We can combine up to 100 components into one tubing set, depending on the customer’s individual requirements. Thereby we assemble specially extruded tubing, standard components and customized molded parts.

Manufacturing technologies
- Application-specific and cost-effective design of the sets
- Semi-automated assembly lines in the clean room
- 100% control of critical characteristics such as leak tightness
- Non-sterile or sterile delivery of the sets
Automation

We have safe and efficient automation solutions, from manual through semi-automatic to fully automatic assembly and production lines. Together with you, we adapt the technical implementation and system concepts according to your wishes and the required capacity.

Micro cannula – an example for RAUMEDIC automation

- Micro extrusion
- Fully automated assembly with tip forming and flaring of the cannula end
- 100% integrated camera inspection of defined quality characteristics

Due to their generally miniscule size, our catheter systems make minimally invasive procedures possible and can be precisely navigated to the origin of the disease. They are therefore useful in clinical diagnostics as well as in therapy, and reduce the time needed for interventions and, as a consequence, the stress for the patient.

Integration of electronic components

With our continuous development of new technologies, we can integrate even the smallest electronic components and cameras into catheter systems.

Manufacturing technologies

- Micro assembly
- Soldering e.g. of wires, cables
- Bonding of microchips
- Assembly of cameras, memory chips, etc.
- Electronic calibration
- Testing of mechanical and optical properties
- Testing of measurement function
- Packaging and sterilization
- Support for CE certification

In whatever quantities you may be planning, RAUMEDIC offers manual, semi-automated or fully automated assembly processes to meet your needs.

Disposable camera for use in the field of medical endoscopy, among other fields.
Implants are used in a wide variety of medical disciplines. An example is drainage catheters in urology.

Short-term implants that remain in the body for less than 29 days differ from long-term implants (> 29 days), which must meet particularly high regulatory requirements.

Only certified materials such as silicone and polyurethane are used for these applications. The special feature of these materials is their high purity, which makes them an ideal choice for implants.

RAUMEDIC processes implant-tested materials with advanced manufacturing technology and precise molded parts.

**Manufacturing technologies**

- Silicone and polyurethane extrusion
- Silicone injection molding
- Printing
- Introducing perforations (punching, drilling)
- Assembly of connectors and cuffs
- Biological and toxicological tests and tests according to ISO 10933
- Customized packaging and sterilization
- Support for CE certification

Together with you, we will develop your product – from the initial idea to series production.

Sophisticated products such as long-term implants, catheter systems, complex tubing sets or other medical devices require many years of experience and extensive knowledge. RAUMEDIC combines these core competencies and offers system solutions from a single source.

Our experts will advise you on materials and raw material selection, on our production technologies for extrusion and injection molding and the assembly of complex systems. We can also help you with packaging and sterilization.

RAUMEDIC is your development partner for customized and high-quality product systems in the medical and pharmaceuticals industry. Contact us for your tailor-made solution!
Global service – what can we do for you?

Thanks to our extensive sales network, you can get personal, on-site support anywhere in the world.

**Headquarters in Europe**
RAUMEDIC AG
Hermann-Staudinger-Str. 2
95233 Helmbrechts
Germany
Phone: +49 9252 359 0
E-mail: info@raumedic.com

**Headquarters in America**
RAUMEDIC INC.
235 Broadpointe Drive
Mills River, NC 28759
USA
Phone: +1 828 684 8870
E-mail: usa@raumedic.com

**Sales offices worldwide**

**Asia/Australia**
RAUMEDIC Pte Ltd
140 Paya Lebar Road #05-09
A-Z Building
Singapore 409015
Singapore
Phone: +65 6702 2001
E-mail: info@raumedic.com

**Southern Europe**
RAUMEDIC SRL
Via S. Maddalena 1
20900 Monza
Italy
Phone: +39 039 3900 816

**Germany**
RAUMEDIC AG
Gallische Straße 2
63128 Dietzenbach
Germany
Phone: +49 6074 69651 0

**Western Europe**
RAUMEDIC AG
Rte du Petit-Moncor 1A
1752 Villars-sur-Glâne
Switzerland
Phone: +41 2640 970 40

RAUMEDIC SARL
5 rue Alphonse Bouffard-Roupé
Parc de l’Oppidum – Bât E
38500 Voiron
France
Phone: +33 476 935 220

**Northern Europe**
RAUMEDIC UK LTD.
C-TRIC Building
Altnagelvin Hospital Complex
Glenshane Road
Derry/Londonderry
BT47 6SB
Northern Ireland
Phone: +44 2871 611 345

**Central and Eastern Europe**
RAUMEDIC AG
Represented by
REHAU Gesellschaft m.b.H.
Industriestraße 17
2353 Guntramsdorf
Austria
Phone: +43 2236 2468 4317