Self-disclosure

of interco Group GmbH

General information about the company

Company	interco Group GmbH
SRN	DE-MF-000005334
Address	Im Auel 50 D 53783 Eitorf
Telephone	+49 2243 8807 0
Fax	+49 2243 8807 29
E-mail	info@interco.gmbh
Internet	www.interco.gmbh
Legal form	GmbH
Trade register no.	HRB 3140 AG Siegburg
VAT no.:	DE811766765
CEO	Janina Markwald-Jänicke, Mario Markwald

Information about the company

Year of foundation	1989
Sales revenues	see German Federal Gazette
Customer industries	Medical supply stores Rehabilitation specialist trade Health centers Clinics and hospitals Medical device manufacturers Mechanical engineering companies Various different skilled trades

Quality management

Quality management system	DIN EN ISO 9001:2015 DIN EN ISO 13485:2016 Certified by Technische Überwachung Hessen GmbH
QMR	Ute Markwald
Compliance Officer	Ute Markwald
Quality policy	Our structured management system is based on measures that serve the continuous improvement of products, processes and services. This makes us a reliable partner and employer for our customers and employees.
Association	Member of the Spektarisverband (German Hightect Industry Association) and the Qualitätsverbund Hilfsmittel (QHV) (Quality Association for Auxiliary Devices) Member of rehaKIND e.V. Internationale Fördergemeinschaft Kinder- und Jugendrehabilitation (rehaKIND e.V. International support association for child and youth rehabilitation)

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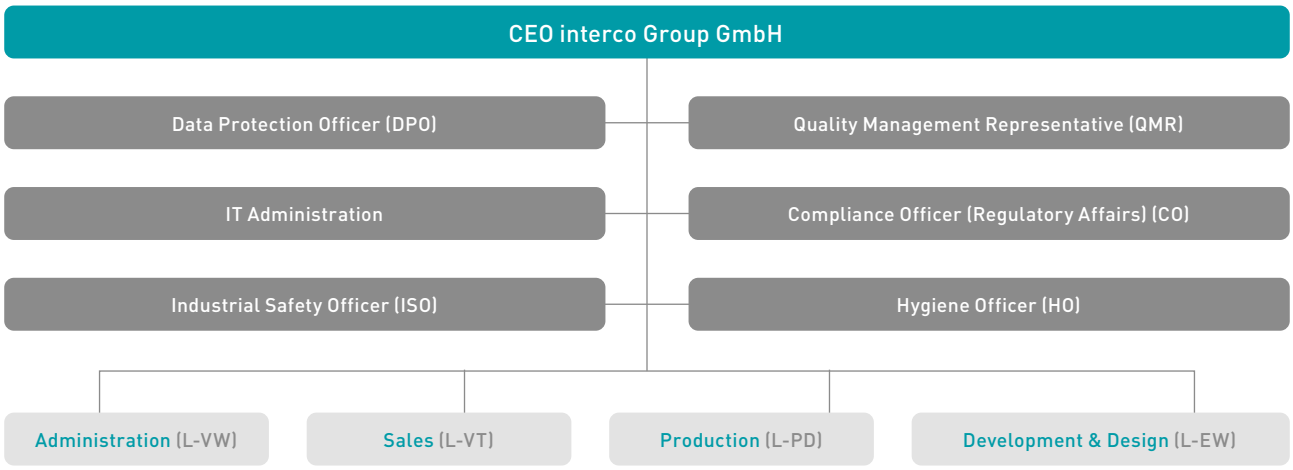
Organizational chart



Contact person

CEO	Janina Markwald-Jänicke Mario Markwald	janina.markwald@interco.gmbh mario.markwald@interco.gmbh
QMR / CO / MSO	Ute Markwald	msib@interco.gmbh
Customer Service		info@interco.gmbh
Sales	Janina Markwald-Jänicke	janina.markwald@interco.gmbh
Accounting	Sonja Köster	buchhaltung@interco.gmbh

Terms of delivery and payment, bank details

Terms of delivery	ex factory
Terms of payment	within 14 days less 2% discount or 30 days net
Bank details	Kreissparkasse Köln BIC: COKSDE33XXX IBAN: DE48 3705 0299 0003 0461 25

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Products and Services

CE labelled products

- Undercarriages (series products) to accommodate seating systems (seat shells) MINY®, SIMPLY LIGHT, SIMPLY®, ROOMY® NE, ECONOMY®
- Standardised seating systems MAGICLIGHT®, MAGICLINE®, ORTHOLIGHT®
- Seating systems individually customised with minor deviations from the standard ORTHOLIGHT®, ERGOLINE®

These products are assigned to a risk class according to Article 51, MDR and undergo the conformity assessment procedure according to Article 52, MDR in accordance with the risk class. By issuing the EU declaration of conformity and affixing the CE conformity marking, we declare that the products meet the essential safety and performance requirements. We provide proof by preparing the technical documentation in accordance with Annex II and III. The products bear a unique serial number and a UDI.

Custom-made products (SA / SO)

- AKTIVLINE Individual
- AKTIVLINE LIGHT
- AKTIVLINE E-Mobil

These three AKTIVLINE types are generally custom-made according to patient requirements. They are subject to the classification and conformity assessment procedure and are labelled as a custom-made product for a named patient in accordance with the EU regulation. In principle, each custom-made product is also marked with a unique serial number. There is no UDI for the individual AKTIVLINE versions.

- ORTHOLIGHT as SA
- ERGOLINE Passiv as SA
- Other seating systems or positioning systems, which are specially manufactured to customer requirements
- Undercarriages as SA

These products are generally custom-made according to patient requirements. They are subjected to the classification and conformity assessment procedure and are adequately labelled in accordance with the EU Regulation. As a matter of principle, each custom-made product is also marked with a unique serial number. There is no UDI for the individual versions of the products.

Accessories for medical devices

- DYNALINE® Fixation aids
- ALULINE® Components for seating systems

These products are assigned to a risk class according to Article 51, MDR and undergo the conformity assessment procedure according to Article 52, MDR in accordance with the risk class. By issuing the EU declaration of conformity and affixing the CE conformity marking, we declare that the products meet the essential safety and performance requirements. We provide proof by preparing the technical documentation in accordance with Annex II and III. The products bear a unique batch number and a UDI.

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Standard articles / products / accessories	In principle, materials as well as various holders etc. are not considered to be medical devices in their own right. They can neither be assigned a clear purpose nor are they to be assigned to a medical device. Customers who purchase materials and non-CE-marked accessories are of course free to use them. They must not lose sight of the EU Regulation when using the materials and must comply with the regulations when processing them further. Individual certificates for the materials, such as safety certificates and/or biocompatibility, are not issued individually in favour of the favourable prices. The interco Group!'s self-disclosure serves as proof in each case.
Materials / accessories	Custom-made articles/products are not subject to the labelling obligation for accessories. They do not count as independent medical devices. These articles are only manufactured on a contract basis according to customer-specific requirements. The intended purpose of the article/product is determined by the client, who is also responsible for the product labelling. The interco Group! maintains the technical documentation for the customer. Examples of customer-specific products are special undercarriages, special brackets, special fixation aids, etc.
Repair materials / repair kits	These materials are not considered to be medical devices in their own right. The reprocessor / new reprocessor is responsible for the proper installation/ attachment, unless he has been explicitly commissioned and authorised by the manufacturer. Reprocessors are also subject to the EU Regulation.
Services	Technical consulting services, construction and design, education and training

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Product conformity and material specifications

Declarations of Conformity

According to DIN EN ISO 13485:2016 Sec. 3.10, interco Group GmbH, as a manufacturer of Class I medical devices, is responsible for the design and/or manufacture of a medical device and for compliance with statutory requirements. In the EUDAMED database, interco Group GmbH is registered as a manufacturer with the SRN DE-MF-000005334 in accordance with Art. 2 No. 30 of Regulation (EU) 2017/745.

The conformity assessment is performed in accordance with (EU) Regulation 2017/745 of the European Parliament and the Council of 05 April 2017 concerning medical devices, Annex IV, Annex IX, Chapter 1.

The declarations of conformity can be found in the annex of the instructions for use and are handed out with each medical device. They can be requested and checked by the responsible authorities at any time with detailed information on the product (article no., serial no. and/or patient name). According to Annex XIII of Regulation (EU) 2017/745 of the European Parliament and of the Council of 05 April 2017 concerning medical devices, special declarations and documentation are kept for custom-made products, which can be viewed and checked at any time by the competent authorities. Accessories for medical devices are to be marked separately as such and used in accordance with their intended purpose.

Materials used

The following raw materials are used to manufacture the Class 1 medical devices and their accessories made by interco Group GmbH:

- Metals (aluminum, steel, stainless steel)
- Plastics (POM, PA6, PTEG)
- Wood (beech wood for therapy tables)
- Foams (polyurethane foam, hard foam, azote foam, neoprene)
- Upholstery fabrics (mesh material, Trevira CS fabrics, artificial leather, Dartex with ÖKO TEX Standard 100 certificates)
- Powder coatings
- DIN and standard parts

All materials are classified as harmless to health. Direct skin contact of the patients may be possible with the upholstery fabrics and the materials used for the therapy tables (beech wood or PETG).

Biocompatibility and toxicity

All materials used by interco Group GmbH that may come into direct bodily contact have been tested for biocompatibility and/or cytotoxicity. The tests according to EN ISO 10993 are available and are regularly monitored by the responsible regulatory authority. The test results are part of the technical documentation according to Annex II of the Regulation (EU) 2017/745 of the European Parliament and the Council of 05 April 2017 concerning medical devices.

Flammability

The upholstery fabrics used by interco Group GmbH are tested according to DIN EN 1021-1 and 1021-2. The verification documents are part of the technical documentation according to Annex II of the Regulation (EU) 2017/745 of the European Parliament and the Council of 05 April 2017 concerning medical devices.

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Packaging	Since February 2019, interco Group GmbH has been registered as a manufacturer of packaging subject to system participation pursuant to §9 VerpackG (German packaging law) under the registration number DE4459410411652. Transport cartons and transport foils are not subject to the system participation obligation. Shipping packaging of all kinds is subject to the obligation to participate. interco Group GmbH is a member of the Dual System, so that shipping packaging disposal is ensured.
Disposal guidelines	Within the framework of the Ordinance on Commercial Waste and in accordance with § 28 of the Ordinance on Waste Recovery and Disposal, interco Group GmbH is registered as a producer of commercial waste. The producer number is: E38204115(2) There are special disposal contracts for the types of waste produced with authorized and approved disposal companies.
Supply Chain Sourcing Obligations Act	With reference to the German Supply Chain Act, which will come into force in 2023, interco Group GmbH pursues the following position: The German Supply Chain Act is aimed at companies that are based in Germany and employ more than 3,000 people (at least for the year 2023). Since interco does not meet these criteria, interco is only indirectly affected – in connection with an increasing duty of care along supply chains. In line with this corporate duty of care and in order to anticipate future developments, interco is working on a sustainable alignment of its supply chains. With the help of various processes implemented in quality management, new business partners are screened and existing suppliers are regularly evaluated. The implementation of corporate guidelines and the signing of the Supplier Code of Conduct are taken into account in the permanent supplier assessments and are intended to ensure that the standards set by interco are complied with and that negative ecological and social impacts are successively minimized along the supply chains. The measures taken in this regard are based on the common guidelines of a corporate duty of care.

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General conditions and specifications

Statutory regulations	We respect and adhere to the statutory regulatory conditions with regard to work, the German Minimum Wage Law (MiLoG), fire and environmental protection, humanity and safety.
Working conditions	We strive to provide our employees with a working environment that promotes maximum efficiency. Health and safety are of paramount importance here. Our employees are called upon to avoid any danger to people and the environment.
Environment	The environment must be protected. We do not work with hazardous substances and try to integrate environmental aspects into our daily work and thinking and to pass these approaches on to our suppliers if necessary. Our employees are frugal in using the resources provided to us.
Ethics	Respecting human dignity and mutual respect for each other are a matter of course for us. We do not discriminate in any way. We reject child labor.
Risk management	The risk-based approach forms the basis of our management system. Risks make it possible to deal constructively with opportunities and show the company and its employees how to become even better.
Conduct towards interested parties	The company undertakes to ensure fair competition within the framework of the statutory requirements. The company's position on the market is not used unlawfully with regard to competition and antitrust law. Agreements with customers are documented as clearly and unambiguously as possible and executed accordingly in our daily work. Our suppliers are selected solely on the basis of their competitive criteria (quality, price and performance, suitability of their products and services).
Handling information	Within the scope of our possibilities we always strive to guarantee the greatest possible security of the data and information made available to us, as well as the documented information stored by us according to the state-of-the-art technology. Our employees are obliged to treat all internal and external information received in the course of their work confidentially.
Data protection	Within the framework of the General Data Protection Regulation (GDPR), we continue to commit ourselves to the trustworthy and secure handling of order-related / person-related and/or personal data transmitted by you to our company or to employees of our company. Without your prior consent, only data will be processed which is necessary for the creation or processing of your order within the framework of the customer-supplier relationship, or which must be stored due to legal requirements (e.g. for custom-made products according to the German Medical Device Regulation). The duration of the retention periods corresponds at least to the statutory requirements. You have the right to receive information, to correct, delete, restrict, transfer data, revoke, or object in written form at any time. The DSO Ute Markwald is responsible for the proper handling of your data at interco Group GmbH.

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CERTIFICATE

for a management system as per

EN ISO 13485:2016/AC:2018, EN ISO 13485:2016/A11:2021

Evidence of conformity has been furnished.

Certificate registration No.:
73 105 6351

Certificate valid from:
2025-05-09 **to:** 2028-05-01

previous certificate was valid until:
2025-05-01

interco Group GmbH
Im Auel 50
53783 Eitorf / Germany

Scope :
Development, manufacture, service and distribution of active and non-active medical medical products, in particular rehabilitation aids and wheelchairs

DAkkS Deutsche Akkreditierungsstelle D-ZM-14137-01-00

Dr. M. Ponick
Head of Certification body
Release: Darmstadt 2025-05-09
Certification Body of TÜV Hessen

This certification confirms the introduction and maintenance of the Management system specified above and is monitored regularly. The current validity is verifiable at www.proficert.de. Original certificates contain a glued hologram.
TÜV Technische Überwachung Hessen GmbH, Robert-Bosch-Strasse 16, 64293 Darmstadt, Germany Phone +49 6151/600331 Rev-GB-2408 Translation of German original

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CERTIFICATE

for a management system as per

DIN EN ISO 9001:2015

Evidence of conformity has been furnished.

Certificate registration No.:
73 100 6351

Certificate valid from:
2025-05-09 **to:** 2028-05-01

previous certificate was valid until:
2025-05-01

interco Group GmbH
Im Auel 50
53783 Eitorf / Germany

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