



SCHOTT
glass made of ideas

FIOLAX[®]

Special Glass Tubes for
Pharmaceutical Packaging

SCHOTT is an international technology group with more than 125 years of experience in the areas of specialty glasses and materials and advanced technologies. With our high-quality products and intelligent solutions, we contribute to our customers' success and make SCHOTT part of everyone's life.

With a production capacity of more than 140,000 tons and production sites in Europe, South America and Asia, SCHOTT Tubing is one of the world's leading manufacturers of glass tubes, rods and profiles. Approximately 60 glass types are produced in large external diameters and a variety of lengths based on site-overlapping strategies in development, production and quality assurance. SCHOTT Tubing provides customized products and services for international growth markets such as pharmaceuticals and electronics as well as industrial and environmental engineering.



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Innovative Solutions for the Future

Glass Tubing – More than Just Glass

While proudly looking back on more than 125 years of experience and excellence in glass technology, we at SCHOTT have set our sights on the future: our Business Segment Tubing has been a decisive factor in setting market trends thanks to continuous process innovation, combined with sophisticated technologies and SCHOTT's own established know-how.

Glass Tubing – Reliable Supplies around the World

A production capacity of more than 140,000 metric tons and production sites on three continents have made the SCHOTT Group's Business Segment Tubing one of the world's leading suppliers of glass tubing. Some 60 different glass types, manufactured in a great variety of sizes, can be supplied to customers in nearly every country around the world, thanks to SCHOTT's extensive distribution network and logistics.

All SCHOTT sites have a common single strategy for research & development, production, quality assurance, and logistics. Ongoing technology transfer processes ensure world leadership in technical expertise. And this is just one of the reasons why identical products comply with the same high quality requirements all over the world.

Glass: The First Choice for Pharmaceutical Packaging

Glass has many advantages over other packaging materials used for pharmaceutical primary packaging: it has only a few components, ensuring reliable information on the chemical resistance and protection of the medicines. In this manner, reliable recommendations can be given to the user on the shelf life of the contents.

This is of great significance in the pharmaceutical field: glass can be very easily sterilized, it is absolutely impervious to gas, has good temperature resistance and withstands high inner pressure; especially when tubing glass is used for packaging. Last but not least, the ecological aspects of this recyclable material are significant.



Outstanding material quality with narrow tolerances – for smooth excellent machine operation and superior product quality. This is the starting point for a perfect pharmaceutical container.





FIOLAX® clear and FIOLAX® amber

Proven Quality Credentials in the Pharmaceutical Market

Otto Schott, founder of the present-day SCHOTT AG, was far ahead of his time.

When he brought the FIOLAX® glass tubing for the manufacture of small medicine bottles (lat. fiola) onto the market in 1911, he created a product that still satisfies the highest quality standards today.

These bottles provide a safe means of storing sensitive pharmaceuticals, generic drugs and modern biotech medicines, because high-quality packaging is the only way to provide people safely with the drugs they need.

Chemical Resistance

Due to its low alkali content, FIOLAX® is a premium glass of the first hydrolytic class. The special glass stands for outstanding chemical resistance,

neutrality, impermeability, and strength. Apart from being a perfect neutral-glass container for injectable solutions, FIOLAX® also makes a particularly safe packaging medium for biotechnological products.

Protection against Ultraviolet Rays

FIOLAX® amber additionally offers effective protection against ultraviolet rays and short-wave visible light. FIOLAX® therefore fulfills the most stringent packaging requirements for the degree of permanent protection demanded for parenteral medicines.

Coating Made to Measure

Upon request, the tubes can also be coated to protect them from scratches, using FDA registered coating materials. FIOLAX® perfectly meets all our

customers' requirements for manufacturing in accordance with the GMP Guidelines.

Tubing Ends for All Applications

FIOLAX® is available in a vast range of end executions to meet any requirements.

For vials and ampoules, closed ends manufactured in accordance with SCHOTT's own DENSOCAN® system are a safe and reliable way to avoid contamination in the process chain, both before and during processing.

For syringes and cartridges, open tubing ends have stood the test of time as the standard solution most preferred by our customers. It goes without saying that other types of tubing ends are also available on request.

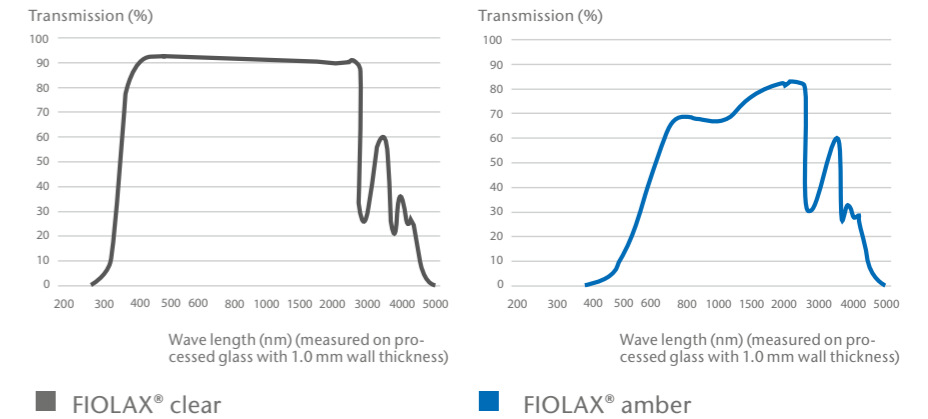
Technical Data

Physical Data

Chemical Resistance

Chemical Composition

main components in approx. weight %



	FIOLAX® clear	FIOLAX® amber
Coefficient of mean linear thermal expansion α (20 °C; 300 °C) according to ISO 7991	$4.9 \cdot 10^{-6} \text{K}^{-1}$	$5.4 \cdot 10^{-6} \text{K}^{-1}$
Transformation temperature T_g :	565 °C	550 °C
Glass Temperature at viscosity η in $\text{dPa} \cdot \text{s}$:		
10^{13} (annealing point)	565 °C	560 °C
$10^{7.6}$ (softening point)	785 °C	770 °C
10^4 (working point)	1,160 °C	1,165 °C
Density ρ at: 25 °C	$2.34 \text{ g} \cdot \text{cm}^{-3}$	$2.42 \text{ g} \cdot \text{cm}^{-3}$

	HGB 1	HGB 1
Hydrolytic Class (ISO 719)	HGB 1	HGB 1
to Ph.Eur.	Type I	Type I
to USP	Type I	Type I
Acid Class (DIN 12 116)	Class S 1	Class S 2
Alkali Class (ISO 695)	Class A 2	Class A 2

	75 %	70 %
SiO ₂	75 %	70 %
B ₂ O ₃	10.5 %	7 %
Al ₂ O ₃	5 %	6 %
Na ₂ O	7 %	7 %
K ₂ O	–	1 %
BaO	–	2 %
CaO	1.5 %	< 1 %
TiO ₂	–	5 %
Fe ₂ O ₃	–	1 %

FIOLAX® for Syringes

Inside Diameter Tolerances up to ± 0.05 mm

FIOLAX® for syringes with extremely accurate filling quantities.

The narrow geometric tolerances typical of FIOLAX® are extremely important for prefillable syringes. On the one hand, FIOLAX® with its precise dimensions optimizes machine operation throughout the manufacturing process, especially during the shaping of the syringe head. On the other hand the narrow inside diameter tolerances ensure very exact filling quantities, especially in syringe systems with scales.

The standard FIOLAX® tubing end execution for syringes has both ends open. In this manner, the open end can be used to form the first mouth thus ensuring consistently high yields. Other dimensions and end executions are also available on request.

The precise inside diameter of FIOLAX® improves the operational reliability of the syringe plunger. Depending on the tube size, we manufacture inside diameter tolerances of up to ± 0.05 mm upon request. It is these extremely narrow inside diameter tolerances which ensure the precisely defined activation forces and even sliding forces of the plunger plug inside the syringe body.



FIOLAX® clear

Selected dimensions for syringes according to ISO 11040-4

Outside Diameter mm	ISO standard	Inside Diameter mm	ISO standard	Bundle Weight appr. kg	Pallet Weight appr. kg
6.85 ± 0.09	± 0.10	4.65 ± 0.08	± 0.10	16.1	1,014.3
8.15 ± 0.10	± 0.10	6.35 ± 0.09	± 0.10	17.8	996.8
10.85 ± 0.10	± 0.10	8.65 ± 0.09	± 0.20	20.0	1,120.0
14.45 ± 0.10	± 0.10	11.85 ± 0.10	± 0.20	20.7	1,014.3
17.05 ± 0.17	± 0.20	14.25 ± 0.15	± 0.20	19.3	1,080.8
22.05 ± 0.17	± 0.20	19.05 ± 0.15	± 0.20	16.3	1,141.0

FIOLAX® for Cartridges and Pen Systems

The resistance of FIOLAX® to compressive stress makes this glass type the first choice for cartridges and pen systems.

The extremely narrow geometric tolerances are not only advantageous for processing and formation but also permit maximum dosing accuracy. This prevents so-called “overfill losses” to the greatest possible extent while increasing dosing accuracy for the user. Inside diameter tolerances of up to ± 0.05 mm are available on request.

A 100 % optical control integrated in the manufacturing process ensures the exceptional quality of FIOLAX®. The standard FIOLAX® tubing end execution for cartridges and pen systems has both ends open. It goes without saying that other dimensions and types of tubing ends are also available on request.

Cartridges made from SCHOTT Tubing meet highest dimensional and cosmetic quality needs



FIOLAX® clear

Standard dimensions for cartridges and pen systems according to ISO 13926-1

Outside Diameter mm	ISO standard	Inside Diameter mm	ISO standard	Bundle Weight appr. kg	Pallet Weight appr. kg
8.65 ± 0.10	± 0.10	6.85 ± 0.09	± 0.10	20.3	1,136.8
10.85 ± 0.10	± 0.10	8.65 ± 0.09	± 0.10	20.0	1,120.0
10.95 ± 0.10	± 0.15	9.25 ± 0.09	± 0.10	19.7	1,103.2
11.60 ± 0.10	± 0.15	9.65 ± 0.09	± 0.10	19.3	1,080.8
14.00 ± 0.11	± 0.15	12.00 ± 0.10	± 0.15	20.6	1,112.4
14.45 ± 0.11	± 0.15	11.85 ± 0.10	± 0.15	20.7	1,014.3
18.25 ± 0.13	± 0.15	16.05 ± 0.13	± 0.15	20.6	988.8
8.65 ± 0.10	± 0.15	6.85 ± 0.09	± 0.15	20.3	1,136.8

FIOLAX® clear

Standard dimensions for dental cartridges according to ISO 11040-1

FIOLAX® for Vials

FIOLAX® for vials effectively protects their content.

Whether or not the properties of medicines remain unchanged over long periods of time literally depends on the containers they are kept in. The outstanding chemical resistance, neutrality and impermeability of FIOLAX® clear and FIOLAX® amber ensures an optimum protection of the contents against premature aging and loss of effectiveness. FIOLAX® amber additionally offers effective protection from ultra-violet rays and short-wave visible light.

And to top everything, all FIOLAX® glass tubes are subjected to 100 % optical control throughout the entire production process. The standard FIOLAX® tubing end execution for vials is DENSOCAN®. It goes without saying that other dimensions and types of tubing ends are also available on request.

DENSOCAN®

DENSOCAN® is a tubing end execution specifically developed by SCHOTT. The tubes are separated with a low particle content and then sealed on the production line by flame. Only a pressure compensation vent remains.

There is no possibility of contamination of the closed tubes during storage, transport or processing. In this way, the lowest possible particle content is ensured.



FIOLAX® clear

Standard dimensions for vials according to ISO 8362-1

Outside Diameter mm	ISO standard	Wall Thickness mm	ISO standard	Bundle Weight appr. kg	Pallet Weight appr. kg
16	± 0.14 ± 0.15	1.0 ± 0.04 ± 0.04	± 0.04	20.0	1,080.0
22	± 0.19 ± 0.20	1.0 ± 0.04 ± 0.04	± 0.04	16.7	1,002.0
24	± 0.19 ± 0.20	1.0 ± 0.04 ± 0.04	± 0.04	16.0	864.0
30	± 0.20 ± 0.25	1.2 ± 0.05 ± 0.05	± 0.05	14.9	804.6

FIOLAX® amber

Standard dimensions for vials according to ISO 8362-1

16	± 0.14 ± 0.15	1.0 ± 0.04 ± 0.04	± 0.04	20.7	1,117.8
22	± 0.19 ± 0.20	1.0 ± 0.04 ± 0.04	± 0.04	11.5	885.1
24	± 0.19 ± 0.20	1.0 ± 0.04 ± 0.04	± 0.04	16.5	891.0
30	± 0.20 ± 0.25	1.2 ± 0.05 ± 0.05	± 0.05	15.4	831.6

FIOLAX® for Ampoules

FIOLAX® for ampoules makes sure that medicines remain safely packed at all times.

Its excellent surface properties provide permanent protection of the contents, ensuring long-term effectiveness of the packed pharmaceuticals. A 100 % optical control of all FIOLAX® glass tubes involves the examination of every single glass tube for contamination or surface flaws. This is the only way to produce high-transparency glass which safely preserves the contents.

The standard FIOLAX® tubing end execution for ampoules is DENSOCAN®. It goes without saying that other dimensions and types of tubing ends are also available on request.



FIOLAX® clear

Standard dimensions for ampoules according to ISO 9187-1

Outside Diameter mm	ISO standard	Wall Thickness mm	ISO standard	Bundle Weight appr. kg	Pallet Weight appr. kg
10.75	± 0.12 ± 0.15	0.50 ± 0.02 ± 0.03	± 0.03	19.0	1,026.0
12.75	± 0.12 ± 0.15	0.50 ± 0.02 ± 0.03	± 0.03	17.0	918.0
14.75	± 0.12 ± 0.15	0.55 ± 0.02 ± 0.03	± 0.03	15.5	837.0
17.75	± 0.14 ± 0.20	0.60 ± 0.03 ± 0.04	± 0.04	13.6	734.4
22.50	± 0.19 ± 0.25	0.70 ± 0.04 ± 0.04	± 0.04	12.6	680.4

FIOLAX® amber

Standard dimensions for ampoules according to ISO 9187-1

10.75	± 0.12 ± 0.15	0.50 ± 0.02 ± 0.03	± 0.03	19.7	1,063.8
12.75	± 0.12 ± 0.15	0.50 ± 0.02 ± 0.03	± 0.03	17.6	950.4
14.75	± 0.12 ± 0.15	0.55 ± 0.02 ± 0.03	± 0.03	16.1	869.4
17.75	± 0.14 ± 0.20	0.60 ± 0.03 ± 0.04	± 0.04	14.1	761.4
22.50	± 0.19 ± 0.25	0.70 ± 0.04 ± 0.04	± 0.04	13.1	707.4

Logistic Solutions

Flexible, Fast and Automated

The right Amounts of the right Products at the right Place and the right Time

The logistics services of SCHOTT's Tubing Business Segment allow greater cost-effectiveness while ensuring smooth delivery of the goods.

SCHOTT's fully IT-supported internal logistics and e-commerce options create ideal conditions for everyday cooperation.

The customer can decide the delivery date and composition as soon as he places the electronic order.

All logistic, production and measuring data are precisely filed for each pallet and are available online for the customer around the clock.

Ordering Round the Clock

FIOLAX® is easy to order over the Internet around the clock. The extensive, login-protected functions under www.schott.com/tubing/ecom make ordering all the easier. Lists of favourites and online order confirmations indicating delivery dates are just a few of the practical options available.

Further information and personalized login data are available by e-mail under kundenservice.rohrglas@schott.com.

Automatic Purchasing – easy stock Replenishment

Vendor Managed Inventory (VMI) - a modern logistics concept that has stood the test of time. Customers do not place orders themselves as usual, but we manage the stock at the customer's warehouse and are responsible for ensuring that the optimum quantity of material is always available at the right time. SAP interfaces allow current stock and demand data to be acquired, from which all the required steps are then generated automatically.

The resulting optimum supplies lower transport costs and reduce the work involved to a minimum.



DENSOPACK®

Tightest packing method + shrink foil
= optimum protection during transport

A Safe Thing

The high quality of our products also requires corresponding handling during transport. To stop the tubes from moving and thus avoiding scratches, SCHOTT has developed DENSOPACK®. Each bundle of tubes is shrink-wrapped with foil at both ends.

This procedure not only means better stability and safety during transport, but the additional shrink wrapping round the whole pallet offers supplementary protection during transport.



Corner protection for pallets

Reduces the risk of breakage and prevents the individual bundles from moving sideways.

All Round Protection

In addition to packaging in accordance with the DENSOPACK® system, corner protection is affixed to the pallet. This can effectively prevent glass breakage and lateral shifting of separate bundles.

Even more effective transportation protection is achieved by shrink wrapping the entire pallet.

This packing ensures that the FIOLAX® special glass tubing reaches the customer in the same quality as it has left the production at SCHOTT Tubing.



Pallet certification

Each pallet comes with a pallet certificate containing important production data.

Certified Supplies

SCHOTT supplies on special pallets specifically adapted to the products. The pallets fit perfectly into standard containers and are ideally suited for storage. Each pallet is provided with a pallet certificate containing the relevant product information specially classifying the glass tubes from a particular pallet: production date, dimensions, production and specification numbers. In connection with labeling the DENSOPACK® units, pallet certification simplifies the customer's incoming goods control and internal documentation. In addition, this information simplifies the machinery set-up as the necessary data can be entered directly into the customer's own system. This provides extra security and saves time.

Scientific Services

Expertise and Troubleshooting

The Scientific Services department provides expert assistance on all issues concerning the properties of our glass tubing, further processing and the great variety of applications of our FIOLAX® glass tubes. Our Scientific Services advisors are optimally equipped with their own chemical and physical laboratories enabling them to offer a wide range of services, from preventive product analysis to independent surveys and customized analyses.

Your direct link

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Our range of activities at a glance

- Fault analysis and recommendations on the manufacturing process
- Advice on specific regulations and standards
- Know-how transfer by training and lectures

Fault Analysis during Processing

Our team is familiar with all aspects of processing our glass tubing into containers, including filling with pharmaceutical products. Our experts can make a vital contribution towards eliminating the cause of problems such as glass breakage, particle formation or surface reactions.

As a result of our longstanding experience, even fault patterns and fault descriptions can point SCHOTT Tubing in the right direction. As and when required, we carry out customized analyses, or examine the whole process chain to find the best possible solution for special requirements. This service is especially beneficial when introducing newly developed products.

Advice on Special Regulations and Standards

In most cases, processing our glass tubing is subject to the observation of various regulations and standards which can vary even from one country to another. The Scientific Services department provides fast and competent help on questions about current DIN and ISO standards, or the main international pharmacopoeia (e.g. Ph.Eur., USP, JP). Our experts themselves actively participate in DIN/NAMED and ISO standardisation committees. As a member of the group of experts within the European Pharmacopoeia Commission, we are permanently involved in standards revision and are therefore always up to date.

Know-how Transfer by Training and Lectures

Our experts pass on their knowledge in training sessions and lectures. No matter whether on the spot with the customer, or at the SCHOTT production sites, the experts from the Scientific Services department offer a complete range of support, from short lectures to intensive full-time training.



FIOLAX® Academy

Especially for customers or pharmaceutical companies we offer a module based training concept which is called FIOLAX® Academy.

Interested customers can book one or several training modules, according to their interests and availability.

The FIOLAX® Academy can be compiled from the following modules.

Tubing Glass Basics

- Glass basics
- Tubing production process
- Plant tour (if the training is held at a SCHOTT Tubing Production site)
- Quality control of FIOLAX® and benefits for the converting/filling process

Drug-Container Interaction

- Alkalinity and its impact
- Extractables and leachables, pH shift
- Protein adsorption
- Light protection

Glass Defects

- Airlines, inclusions, particles
- Stress
- Occurrence and prevention of breakage throughout the converting / filling process

Benchmarking

- Different Type I glasses - 3.3, 5.0, 7.0
- Not every Type I glass is the same - differences in quality
- Tubing or molded? Glass or polymer?

Individual Workshop

- FAQs
- Mix and Match: bring your own topics and questions to a unique knowledge transfer

Regulatory

- International Pharmacopoeia
- International and national standards
- REACH, ROHS, GMP



Quality by SCHOTT

Meet one's own demands

Quality management of all business and technical processes plays a central role in the manufacture of pharmaceutical products, as any deviations from the quality standard may have direct effects on consumer health. We from SCHOTT's Tubing Business Segment, one of the world's leading manufacturers of glass tubing for pharmaceutical primary packaging, take this responsibility very seriously.

The manufacture of products of excellent quality has top priority at all production sites of the Tubing Business Segment. The continuous transfer of know-how ensures identical quality standards worldwide for identical products, with quality levels way above the generally established standards. Quality from SCHOTT, manufactured with state-of-the-art production processes, is measured, inspected and documented 100 %, and can be traced back to the very origin of each production process.

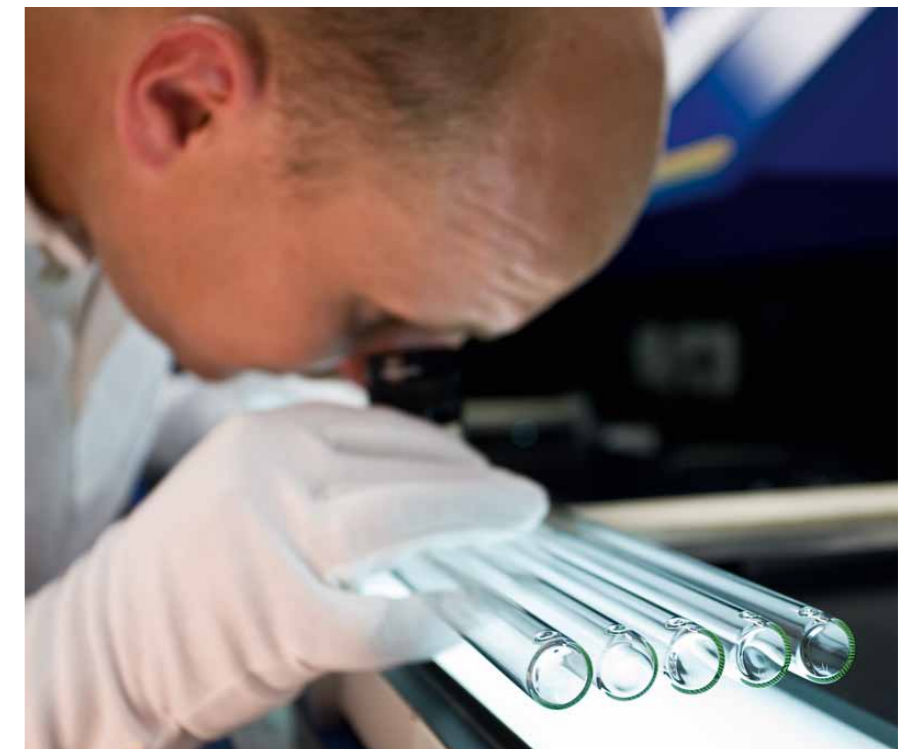
Good Manufacturing Practice (GMP)

The internationally recognized rules and objectives of Good Manufacturing Practice (GMP) are a decisive factor in the production of primary packaging materials for the pharmaceutical industry. Serving as a guideline for production processes and production environment, GMP is a valuable adjunct to and extension of the generally established ISO 9001 standard.

SCHOTT in Mitterteich (formerly SCHOTT-Rohr Glas, Germany), was the world's first glass tubing manufacturer to be certified under the relevant European ISO 15378 standard. The production sites of SCHOTT's Business Segment Tubing in Spain and Brazil are now certified as well according to this standard, while the certification at the Indian production site is in preparation.

SCHOTT's Good Manufacturing Practice and ISO 9001 designed processes go way beyond mere compliance with technical values. All processes have been designed to meet the needs and requirements of all customers in the business of further processing glass tubing by SCHOTT into high-quality primary packaging materials. Glass tubing by SCHOTT ensures valid results while retaining the highest quality standards.

GMP, in its guideline for production processes and production environment (ISO 15378), is both an adjunct to and an extension of the generally established ISO 9001 standard.



Quality control of FIOLAX® clear

Tested and Approved Quality from SCHOTT

Every single glass tube made by SCHOTT is controlled 100 % before it even leaves the production process. Every single measured value is documented and available at any time. Thanks to this stringent level of testing and quality control, SCHOTT helps to make the customers' incoming goods inspection a lot easier.

All of SCHOTT's production lines have both mechanical and optoelectronic precision measuring equipment designed to inspect every single tube and detect any variation from the defined tolerances. Any tube found to be outside the tolerance limits will be automatically rejected. The electronic control system signals the quality status of the process to the machine operator, who is then able to react at short notice.

In addition to electronic measurements on the production lines, random samples are taken at set intervals throughout the production process. Samples taken undergo chemical, physical and visual tests in SCHOTT's in-house laboratory to confirm and extend the results gathered during automatic inspection.

Whenever finished tubes are packaged and ready for shipment, all related measuring results gathered are archived together with the relevant packaging information for later access. That way, up to 250 different sets of data and measuring values are readily available for retrieval for every single pallet.

Certified Quality

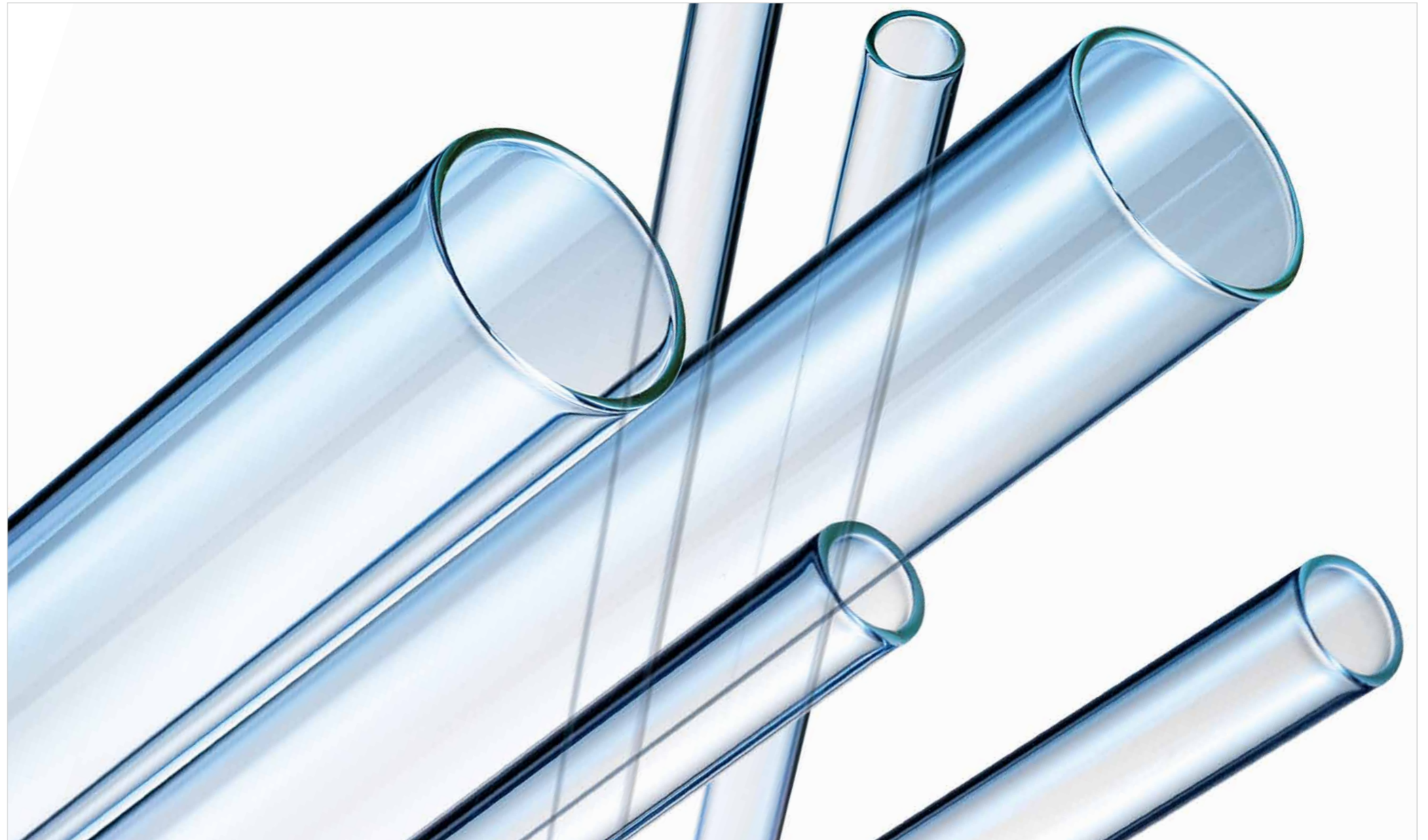
Top quality of all products and processes in all areas and quality leadership for our customers' benefit are among the principal objectives of SCHOTT'S Business Segment Tubing.

Certification according to the following standards testifies the ongoing success of our business policy:

- DIN EN ISO 9001:2008
- ISO 15378:2011
- DIN EN ISO 14001:2004

Automatic quality control

In addition to the customary industrial quality assurance measures based on sampling, SCHOTT also has every single tube inspected by a camera inspection system integrated in the production process. Supplementary to the 100 % inspection integrated in the production process random samples are taken periodically for intense chemical, physical and visual analysis.



How to get here

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