SCHOTT
glass made of ideas

# FIOLAX®

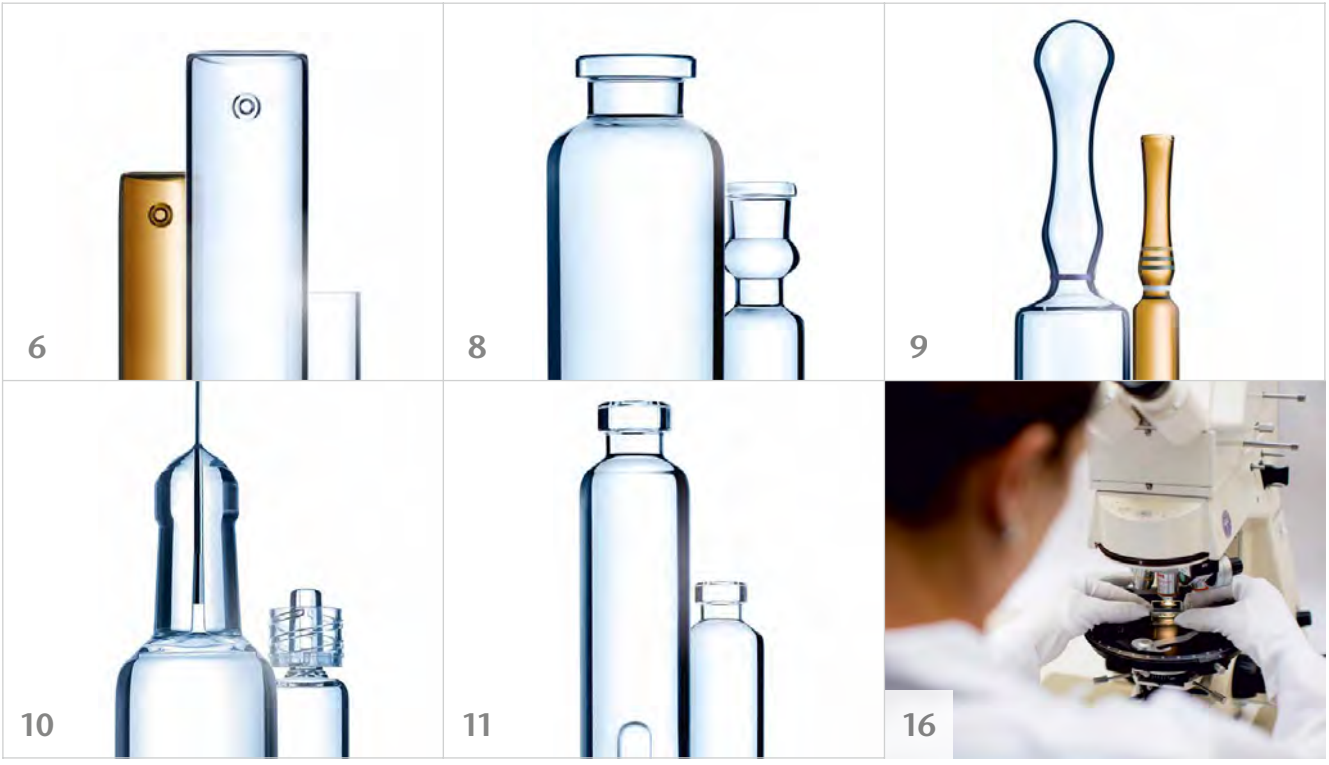
Special Glass Tubing for
Pharmaceutical Packaging

SCHOTT is a leading international technology group in the areas of specialty glass and glass-ceramics. With more than 130 years of outstanding development, materials and technology expertise we offer a broad portfolio of high-quality products and intelligent solutions that contribute to our customers' success.

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.

More than 60 different glass types are produced in a large variety of dimensional and cosmetic specifications based on a standardized production process and a global quality assurance system.

SCHOTT Tubing provides customized products and services for international growth markets such as pharmaceuticals and electronics as well as industrial and environmental engineering.




# Contents

# Innovative Solutions for the Future
## Glass Tubing – More than just Glass

While proudly looking back at more than 130 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

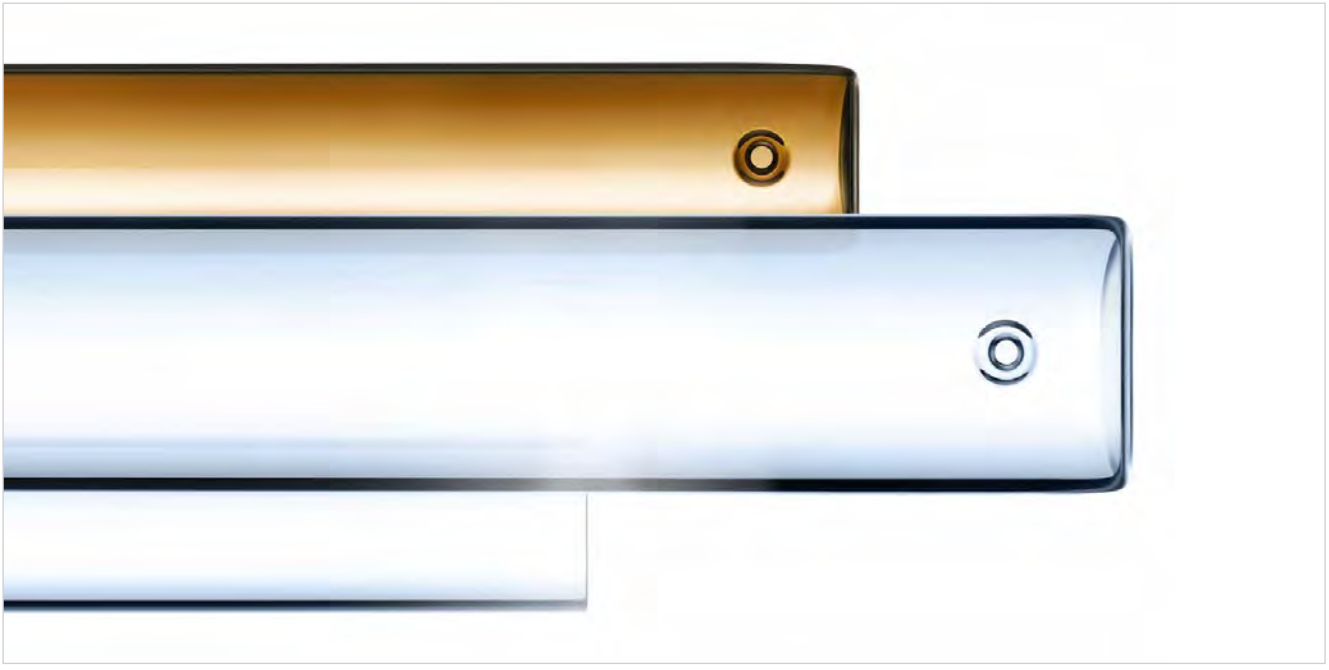
A production capacity of more than 140,000 metric tons and production sites on three continents have made the SCHOTT Group's Business Segment Tubing one of the world's leading suppliers of glass tubing. Some 60 different glass types, manufactured in a great variety of sizes, can be supplied to customers 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) and ampoules onto the market in 1911, he created a product that still satisfies the highest quality standards today. Sensitive pharmaceuticals, generic drugs and modern biotech drugs can be stored safely due to its excellent barrier properties.

### 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.

### Anti-Scratch Coating

Upon request, the tubes can also be coated to protect them from scratches, by using coating materials which are used as a standard emulsifier in the pharmaceutical industry, known as Tween derivative.
FIOLAX® perfectly meets all our customers' requirements for manufacturing in accordance with the GMP Guidelines.

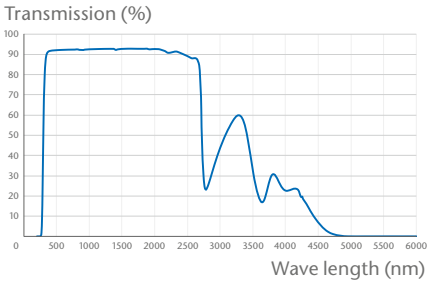
### Tubing Ends for all Applications

FIOLAX® is available in a vast range of end finishes 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.

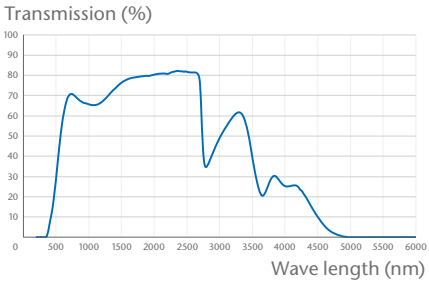
For syringes and cartridges, open tubing ends have stood the test of time as the standard solution most preferred by our customers. It goes without saying that other types of tubing ends are also available on request.

## Technical Data

FIOLAX® clear




FIOLAX® amber




Measured on processed glass with 1.0 mm wall thickness.

## Physical Data

| | FIOLAX® clear | FIOLAX® amber |
|---|---|---|
| Coefficient of mean linear thermal expansion a (20 °C; 300 °C) according to ISO 7991 | $4.9 \cdot 10^{-6} K^{-1}$ | $5.4 \cdot 10^{-6} K^{-1}$ |
| Transformation temperature $T_g$ | 565 °C | 550 °C |
| Glass Temperature at viscosity η in dPa · 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 | $2.34 \text{ g} \cdot \text{cm}^{-3}$ | $2.42 \text{ g} \cdot \text{cm}^{-3}$ |

## Chemical Resistance

| | | |
|---|---|---|
| Hydrolytic Class (ISO 719) | HGB 1 | HGB 1 |
| acc. to Ph.Eur.[1] | Type I | Type I |
| acc. to USP[2] | Type I | Type I |
| acc. to JP[3] | fulfilled | fulfilled |
| Acid Class (DIN 12 116) | Class S 1 | Class S 1 |
| Alkali Class (ISO 695) | Class A 2 | Class A 2 |
| ASTM[4] E 438 | Type I<br>Class B | |

## Chemical Composition

main components in approx. weight %

| | | |
|---|---|---|
| $SiO_2$ | 75 % | 70 % |
| $B_2O_3$ | 10.5 % | 7.5 % |
| $Al_2O_3$ | 5 % | 6 % |
| $Na_2O$ | 7 % | 6.5 % |
| $K_2O$ | – | 1 % |
| BaO | – | 2 % |
| CaO | 1.5 % | < 1 % |
| $TiO_2$ | – | 5 % |
| $Fe_2O_3$ | – | 1 % |

[1] Ph. Eur. = European Pharmaocopeia, [2] USP = United States Pharmacopeial Convention
[3] JP = Japanese Pharmaocopeia, [4] ASTM = American Society for Testing and Materials

# 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 finish for vials is DENSOCAN®. In addition other dimensions and types of tubing ends, for example a First Piece Version, are also available on request.

**DENSOCAN®**

DENSOCAN® is a tubing end finish specifically developed by SCHOTT. The tubes are separated with a low particle content and then sealed on the production line by flame. Only a vent hole 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 | | Best value* | ISO standard | Wall Thickness mm | | ISO standard | Bundle Weight appr. kg | Pallet Weight appr. kg |
|---|---|---|---|---|---|---|---|---|
| 16 | ± 0.14 | up to ± 0.12 | ± 0.15 | 1.0 | ± 0.04 | ± 0.04 | 20.0 | 1,080.0 |
| 22 | ± 0.19 | up to ± 0.17 | ± 0.20 | 1.0 | ± 0.04 | ± 0.04 | 16.7 | 1.002.0 |
| 24 | ± 0.19 | up to ± 0.17 | ± 0.20 | 1.0 | ± 0.04 | ± 0.04 | 16.0 | 864.0 |
| 30 | ± 0.20 | - | ± 0.25 | 1.2 | ± 0.05 | ± 0.05 | 14.9 | 804.6 |

**FIOLAX® amber**
Standard dimensions for vials according to ISO 8362-1

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| 16 | ± 0.14 | up to ± 0.12 | ± 0.15 | 1.0 | ± 0.04 | ± 0.04 | 20.7 | 1,117.8 |
| 22 | ± 0.19 | up to ± 0.17 | ± 0.20 | 1.0 | ± 0.04 | ± 0.04 | 11.5 | 885.1 |
| 24 | ± 0.19 | up to ± 0.17 | ± 0.20 | 1.0 | ± 0.04 | ± 0.04 | 16.5 | 891.0 |
| 30 | ± 0.20 | - | ± 0.25 | 1.2 | ± 0.05 | ± 0.05 | 15.4 | 831.6 |

*We also offer “best value” production with even tighter tolerances based on your specific requirements, which is available upon request.

# 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 finish 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 | 19.0 | 1,026.0 |
| 12.75 | ± 0.12 | ± 0.15 | 0.50 | ± 0.02 | ± 0.03 | 17.0 | 918.0 |
| 14.75 | ± 0.12 | ± 0.15 | 0.55 | ± 0.02 | ± 0.03 | 15.5 | 837.0 |
| 17.75 | ± 0.14 | ± 0.20 | 0.60 | ± 0.03 | ± 0.04 | 13.6 | 734.4 |
| 22.50 | ± 0.19 | ± 0.25 | 0.70 | ± 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 | 19.7 | 1,063.8 |
| 12.75 | ± 0.12 | ± 0.15 | 0.50 | ± 0.02 | ± 0.03 | 17.6 | 950.4 |
| 14.75 | ± 0.12 | ± 0.15 | 0.55 | ± 0.02 | ± 0.03 | 16.1 | 869.4 |
| 17.75 | ± 0.14 | ± 0.20 | 0.60 | ± 0.03 | ± 0.04 | 14.1 | 761.4 |
| 22.50 | ± 0.19 | ± 0.25 | 0.70 | ± 0.04 | ± 0.04 | 13.1 | 707.4 |

# FIOLAX® for Syringes

## Inside Diameter Tolerances up to ± 0.05 mm

**FIOLAX® for syringes supports the dosing accuracy of a syringe system.**
The low geometric tolerances of FIOLAX® are extremely important in the production and processing of pre-fillable syringes.
FIOLAX® facilitates machinability during the processing process thanks to its uniform wall thickness distribution, in particular when shaping the barrel of a syringe. What's more, the tight inside diameter tolerances can contribute to uniform gliding forces and enhanced dosing accuracy.

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

**FIOLAX® clear**
Selected dimensions for syringes according to ISO 11040-4

| Outside Diameter mm | | Best value* | ISO standard | Inside Diameter mm | | Best value* | ISO standard | Bundle Weight appr. kg | Pallet Weight appr. kg |
|---|---|---|---|---|---|---|---|---|---|
| 6.85 | ± 0.08 | up to ± 0.05 | ± 0.10 | 4.65 | ± 0.08 | up to ± 0.05 | ± 0.10 | 16.1 | 1,014.3 |
| 8.15 | ± 0.09 | up to ± 0.05 | ± 0.10 | 6.35 | ± 0.09 | up to ± 0.05 | ± 0.10 | 17.8 | 996.8 |
| 10.85 | ± 0.09 | up to ± 0.05 | ± 0.10 | 8.65 | ± 0.09 | up to ± 0.05 | ± 0.20 | 20.0 | 1,120.0 |
| 14.45 | ± 0.10 | up to ± 0.09 | ± 0.10 | 11.85 | ± 0.10 | up to ± 0.09 | ± 0.20 | 20.7 | 1,014.3 |
| 17.05 | ± 0.15 | up to ± 0.09 | ± 0.20 | 14.25 | ± 0.15 | up to ± 0.09 | ± 0.20 | 19.3 | 1,080.8 |
| 22.05 | ± 0.17 | up to ± 0.09 | ± 0.20 | 19.05 | ± 0.15 | up to ± 0.09 | ± 0.20 | 16.3 | 1,141.0 |

*We also offer "best value" production with even tighter tolerances based on your specific requirements, which is available upon request.

# FIOLAX® for Cartridges

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

Narrow geometrical tolerances are not only advantageous for the processing and converting process, but also support the functionality of the cartridges that are frequently used in pen or pump systems. Overfill losses can be reduced and dosage accuracy, particularly in the case of multiple doses, is increased for the user. Internal diameter tolerances of up to ± 0.05 mm as a zero defect criteria (API = All points in) can be produced upon request, depending on the dimensions.

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

**FIOLAX® clear**
Standard dimensions for cartridges according to ISO 13926-1

| Outside Diameter mm | | Best value* | ISO standard | Inside Diameter mm | | Best value* | ISO standard | Bundle Weight appr. kg | Pallet Weight appr. kg |
|---|---|---|---|---|---|---|---|---|---|
| 8.65 | ± 0.09 | up to ± 0.05 | ± 0.10 | 6.85 | ± 0.09 | up to ± 0.05 | ± 0.10 | 20.3 | 1,136.8 |
| 10.85 | ± 0.09 | up to ± 0.05 | ± 0.10 | 8.65 | ± 0.09 | up to ± 0.05 | ± 0.10 | 20.0 | 1,120.0 |
| 10.95 | ± 0.09 | up to ± 0.05 | ± 0.15 | 9.25 | ± 0.09 | up to ± 0.05 | ± 0.10 | 19.7 | 1,103.2 |
| 11.60 | ± 0.09 | up to ± 0.05 | ± 0.15 | 9.65 | ± 0.09 | up to ± 0.05 | ± 0.10 | 19.3 | 1,080.8 |
| 14.00 | ± 0.10 | up to ± 0.07 | ± 0.15 | 12.00 | ± 0.10 | up to ± 0.07 | ± 0.15 | 20.6 | 1,112.4 |
| 14.45 | ± 0.10 | up to ± 0.07 | ± 0.15 | 11.85 | ± 0.10 | up to ± 0.07 | ± 0.15 | 20.7 | 1,014.3 |
| 18.25 | ± 0.13 | up to ± 0.07 | ± 0.15 | 16.05 | ± 0.13 | up to ± 0.07 | ± 0.15 | 20.6 | 988.8 |

**FIOLAX® clear**
Standard dimensions for dental cartridges according to ISO 11040-1

| | | | | | | | | | |
|---|---|---|---|---|---|---|---|---|---|
| 8.65 | ± 0.09 | up to ± 0.05 | ± 0.15 | 6.85 | ± 0.09 | up to ± 0.05 | ± 0.15 | 20.3 | 1,136.8 |

*We also offer "best value" production with even tighter tolerances based on your specific requirements, which is available upon request.

# Packaging and Labelling
## Optimum protection during transportation


**DENSOPACK®**
Tightest packing method + shrink foil
= optimum protection during transport


**Corner protection for pallets**
Reduces the risk of breakage and prevents the individual bundles from moving sideways.


**Pallet certification**
Each pallet comes with a pallet certificate containing important production data.

### 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.

### 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. Furthermore, SCHOTT supplies on special pallets specifically adapted to the products. The pallets fit perfectly into standard containers and are ideally suited for storage. 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.

### Certified Supplies
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 (incl. actual mean value and standard deviation), production and specification numbers. In connection with labeling the DENSOPACK® units, pallet certification simplifies the customer's incoming goods control and internal documentation. This data is also available in our e-commerce system. 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.

# Quality Management
## ISO 15378 (GMP) and ISO 9001

### Management System

Management System
ISO 9001:2015
ISO 15378:2015
www.tuv.com
ID 0091003274

**Germany**

Management System
ISO 9001:2015
ISO 15378:2015
www.tuv.com
ID 9105068726

**Brazil**

Management System
ISO 9001:2015
ISO 15378:2015
www.tuv.com
ID 9105082675

**India**


Certificate

Standard: ISO 9001:2015 and ISO 15378:2015

Certificate Holder: SCHOTT AG
Business Segment Tubing
Erich-Schott-Straße 14
D - 95666 Mitterteich

Scope: Development, production and sales of glass tubing and glass tubing products

Validity: The certificate is valid from 2014-12-01 until 2017-11-30.
First certification 1993 for ISO 9001
First certification 2008 for ISO 15378

2016-06-02 (Change)

www.tuv.com

TÜVRheinland®
Precisely Right.

### GMP is a matter of course for us

In the pharmaceutical industry it is only natural to produce medications and active ingredients according to GMP (Good Manufacturing Practice) guidelines, to ensure the quality of the production processes and environment.
The ISO Standard 15378, which applies particularly to manufacturers of primary packaging material, has been in force since 2006. This standard contains all relevant GMP requirements, thus allowing harmonization with the pharmaceutical requirements for safety and security.

### In fact worldwide

From its beginnings, we contributed to drafting the ISO 15378. Our location in Mitterteich was the first glass tubing manufacturing facility worldwide to be certified according to ISO 15378:2006. The production site in Mainz followed immediately after its production start in 2009 and is also included in Mitterteich's certified quality management system. In 2012 the production facilities in Rio de Janeiro, Brazil and in 2015 the location in Vadodara, India were certified in compliance with ISO 15378.
For many years we have cooperated exclusively with TÜV Rheinland in Germany with regard to all ISO 9001 and ISO 15378 (GMP) certifications – and this also includes the facilities in Brazil and India. This ensures certification according to one high, uniform standard. Additionally, all certifications are accredited by the German accrediting authority DAkkS.
We actively collaborate in the German (DIN[5]) and international (ISO) committees in order to further develop the GMP standard for primary packaging.

### For us GMP means

- Continuous, integrated risk management in our core and support processes, thus in all technical and administrative processes
- Transfer of standards within the BS Tubing production network initiated by our lead plant in Mitterteich
- Change management based on chances and risks
- Pest Control
- Annual GMP trainings for all employees
- Supplier management from selection to validation, approval, support and evaluation
- Risk management policy and cyclic risk assessments
- Complete data logging and archiving to ensure traceability of products in the production process chain (quality and process data)
- Training concepts for employees with respect to GMP
- Maintenance and cleaning plans
- Validation policy and master validation plan
- Data archiving policy and planned data archiving with check of data recoverability

[5] Deutsches Institut für Normung (German Institute for Standardization)

# Quality Management
## Zero Defect Quality Policy

**Every single medication counts – for us this means: Every single piece of tubing counts**

In the medical field, every patient counts and therefore every single medication. The quality of each and every piece of tubing is significant, because our tubing is used to produce a variety of pharmaceutical containers. This requirement is the basis for our corporate-wide objective of a zero defect policy, which we implement in the SCHOTT Tubing Production Department in the form of our perfeXion™ tubing manufacturing process. Within the scope of this process, we have developed precise, high resolution and high frequency measuring systems to reach previously unachievable measuring and sorting reliability. The data generated in the perfeXion™ tubing production process is compiled in a database, now in real time. This means that we also have significantly improved the depth of data on the process and thus the possibility to retrace the pharmaceutical production chain. Meanwhile the new systems enable us to offer quality features such as "zero defect", equivalent to "API = All Points In", meaning that every piece of tubing on a pallet meets the specifications in every single point.

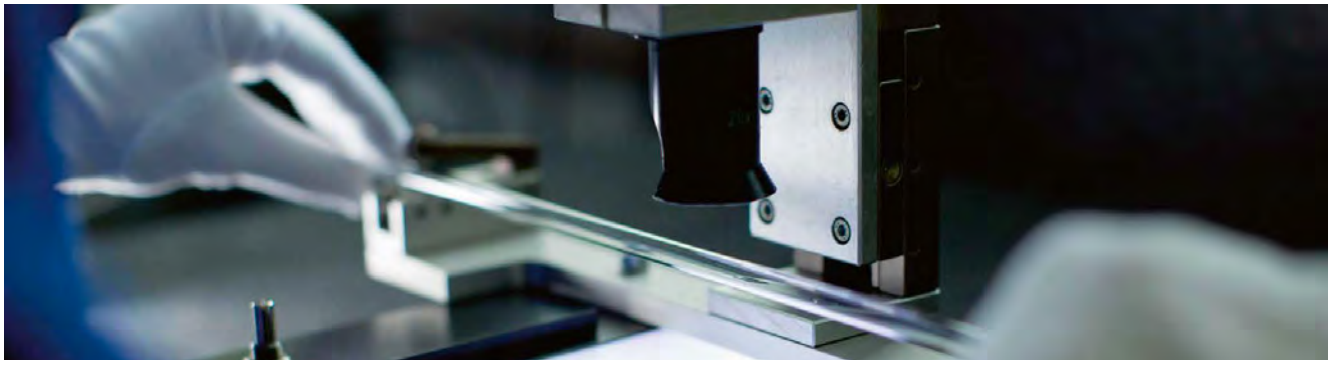
We use two approaches to realize our zero defect policy:

**We produce the highest quality right from the very beginning:**

Based on the data collected by our measuring systems, their high data density and higher measuring accuracy, we were able to improve our process control even further. Among other things, this has made it possible to provide our production staff with the process capability parameters $C_p$ and $C_{pk}$ for an increased number of properties, which are utilized to operationally optimize the quality situation. For example, these statistical values allow us to recognize trends and to proactively correct them. In addition to advancing the development of the overall measuring system for improved measuring and sorting accuracy, we are now increasingly capable of offering and guaranteeing customized specifications with extremely tight tolerances. Incorporated into this process are both our measuring systems, which are validated according to the current version of ISO 15378 (GMP), and the additionally validated process database.

**We inspect each and every piece of tubing 100 %:**

Our measuring systems, which were developed in-house, ensure 100 % inspection of the tubing, even with regard to parameters such as the inside diameter, which were difficult to measure previously. We have also been successful in improving our measuring systems for visual quality characteristics. For example, we can differentiate between open and closed airlines and set these parameters as quality features after agreement. This makes it possible for us to offer individual specifications tailored even closer to our customers' requirements. Within the scope of our continuous improvement process, we will continue to develop our processes according to the zero defect philosophy, allowing us to supply our products with the highest quality for standard as well as customized specifications. This enables our customers to economically produce the highest quality pharmaceutical containers and the pharmaceutical companies to deliver each individual medication to the patient in a secure container.



# Quality Management
## perfeXion™ - The New Era of Quality Processing

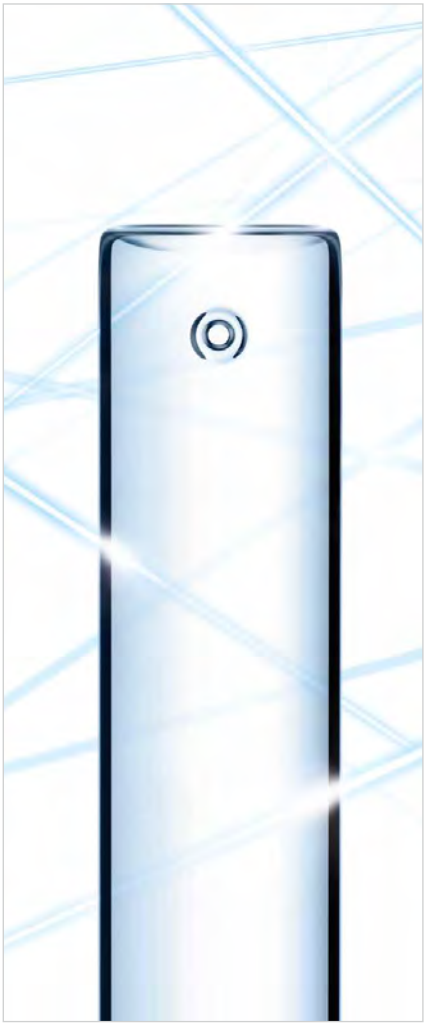
perfeXion™ stands for the transition from statistical quality control to 100 % inspection of each individual FIOLAX® tube. Various interacting online inspection devices, in combination with integrated data collection and data analysis, allow quality parameters of the original tube to be adapted to the container format (syringe, cartridge, vial or ampoule) and customer specification.

### Benefits at a glance:

**perfeXion™ enables more precise geometry:**
A more consistent wall thickness of the initial tube, for instance, facilitates a more precise hot-forming process in geometrically critical container sections, such as the crimp neck of vials or the cones and flanges of syringes. Tightly-toleranced inner diameters of the original tube not only ensure a constant gliding force but also enhance dosing accuracy, in particular for highly concentrated injectable substances in multi-dose devices.

**perfeXion™ facilitates superior cosmetic quality:**
The seamless cosmetic inspection of each individual glass tube over its entire length reduces yield loss in camera-controlled primary packaging production as well as at the end of the value chain at the visual inspection of the filled container. Furthermore, and in particular for cartridges and prefillable syringes, the detection and sorting out of inner open airlines within the original tube contribute to improved container closure integrity by preventing bypass effects.

**perfeXion™ is based on figures, data and facts:**
During the tubing production process, online process- and product-quality data are collected in real-time and transmitted to an industry-standard data management system (PI database). This significantly increased data depth is now available to facilitate the calculation of the statisitical certification data. For the first time, single tube data are used to control and stabilize the tubing production processes. This enables downstream post-processing steps to be efficiently aligned with the tubing quality.



perfeXion™
The New Era of Quality Processing

# Scientific Services
## Expertise and Troubleshooting

The Scientific Services Department of SCHOTT Tubing provides advice and assistance on all questions concerning the properties, processing and versatility of FIOLAX® glass tubing.
From preventive product analysis through independent expert opinions to customer specific analysis, the Scientific Services team offers a wide range of services. This team of well qualified experts is well versed in both the chemical and physical properties of the glass, as well as the pharmaceutical solutions and processes, and can therefore ideally respond to the individual needs and challenges of the converters and pharmacists.

Your direct link

Dr. Folker Steden

Phone: +49 (0)9633/80-253
folker.steden@schott.com

## 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 converting our glass tubing into containers, including filling with pharmaceutical products. Our experts can make a vital contribution towards eliminating the root 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 customised analysis 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, converting 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[6]).
Our experts themselves actively participate in DIN and ISO standardisation committees. As a member of the group of experts within different commitees, 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 several days' training.

[6] Ph. Eur. = European Pharmacopeia, USP = United States Pharmacopeial Convention, JP = Japanese Pharmacopeia

# 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 site)
- Quality control of FIOLAX® and benefits for the converting/filling process

**Drug-Container Interaction**

- Alkalinity and its impact
- pH shift, Extractables and Leachables
- Delamination
- Protein adsorption
- Surface treatments
- Light protection

**Glass Defects**

- Definition and classification of glass defects
- Airlines, inclusions, particles
- Stress
- Occurence and prevention of breakage throughout the converting/filling process

**Benchmarking**

- Glass suppliers: What makes the difference?
- How does the quality of the tubing influence the quality of the final container?
- Tubing or molded? Glass or polymer?

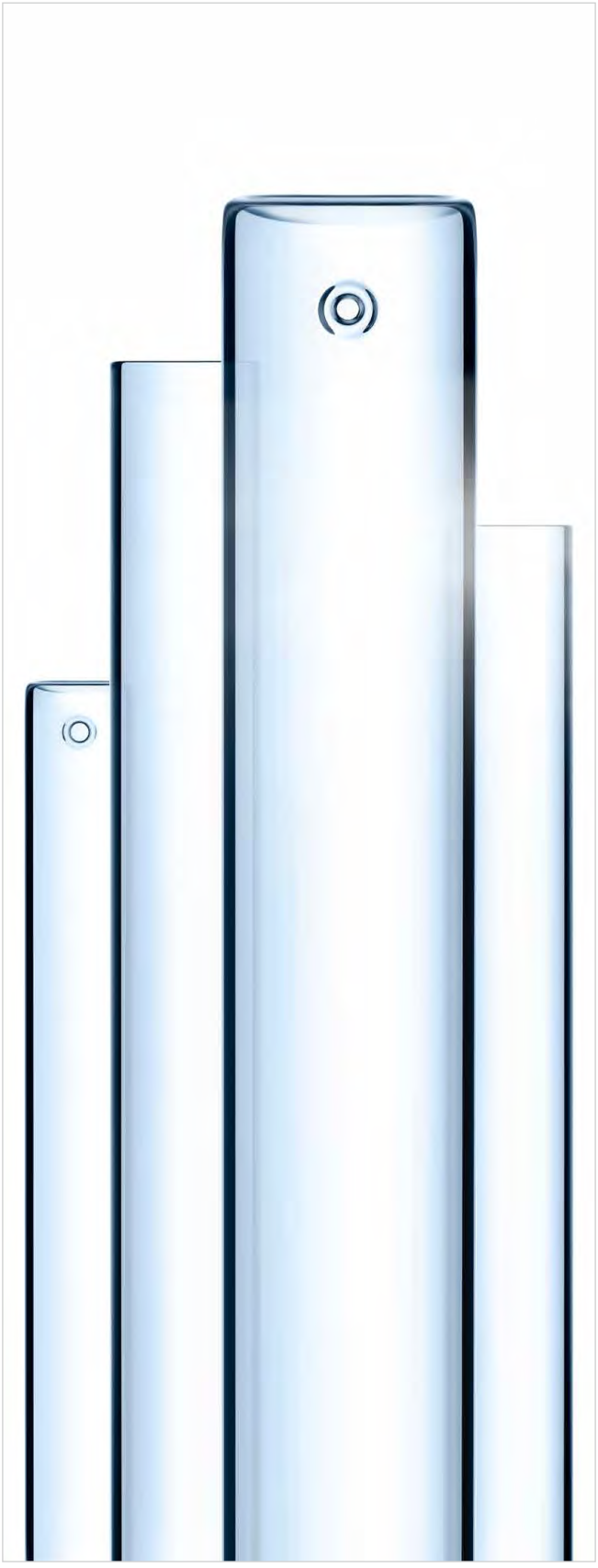
**Individual Workshop**

- 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

If you have any further questions or are interested in a FIOLAX Academy, you can contact us by e-mail directly at fiolax.academy@schott.com - we will be happy to advise you.



# Tubing
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