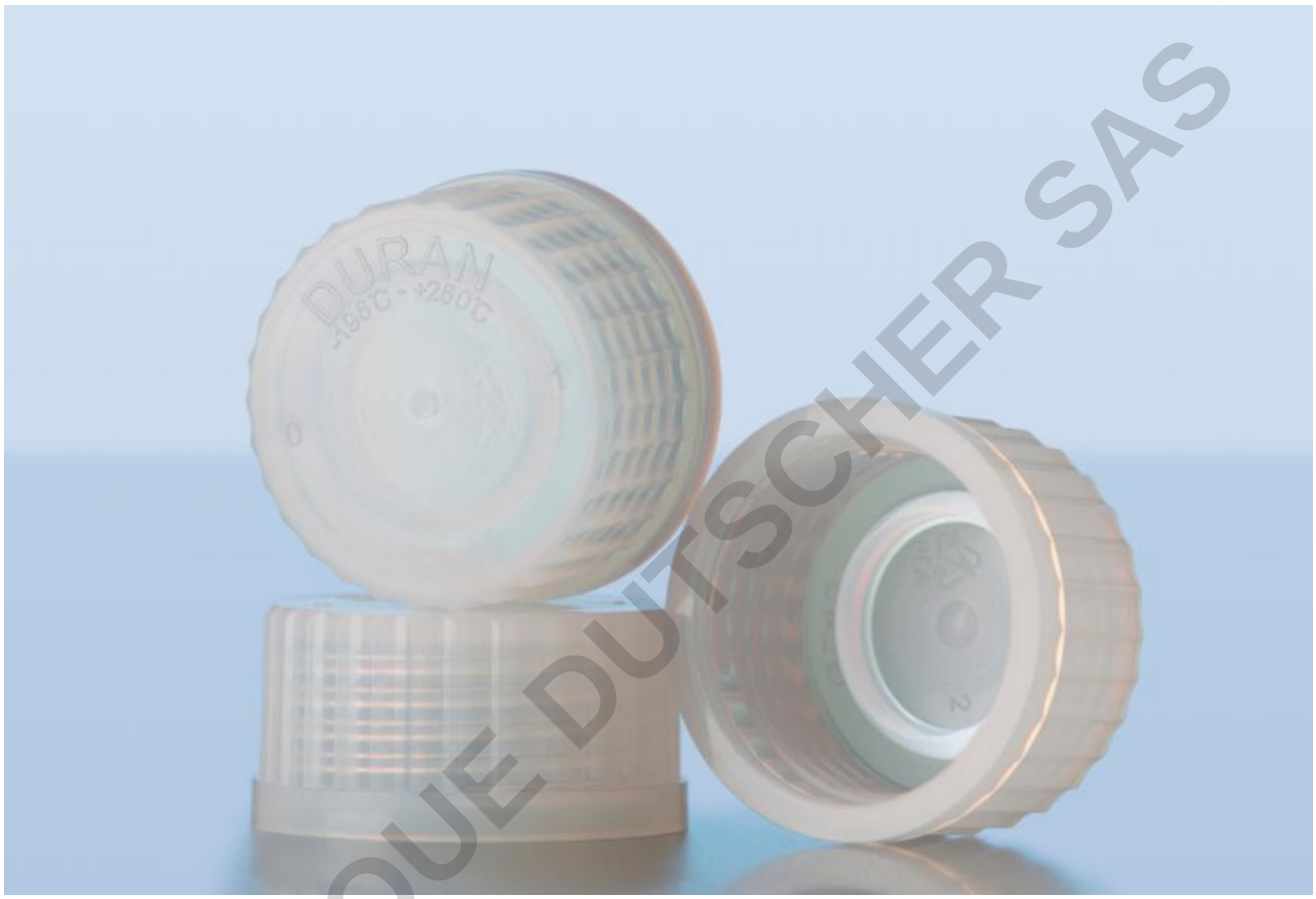
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DWK LIFE SCIENCES



QUALIFICATION DOCUMENTATION
DURAN PURE Premium lip seal cap, GL 45

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Qualification Documentation

DWK LIFE SCIENCES

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Qualification Documentation

Introduction

In the pharmaceutical regulated field, medicine and agent manufacturers are subject to strict requirements, adherence to which is monitored within the framework of inspections.
This qualification documentation, which is a summary of the product and supplier information for operational qualification, was developed for the qualification of our products and the official examination.

Supplier

DWK Life Sciences GmbH
Otto-Schott-Str. 21
D-97877 Wertheim/Main

www.dwk.com

DWK Life Sciences

DWK Life Sciences is a leading global manufacturer of premium laboratory and storage solutions for a wide range of scientific and technical applications.
The DWK Life Sciences offering includes over **25,000 laboratory products, manufactured at 12 sites,** and marketed under the highly recognized brands **DURAN®, WHEATON®** and **KIMBLE®**. Its world-leading and trusted glass is complemented by an innovative research and life science portfolio.
Worldwide, **1,700 people** are dedicated to developing and delivering superior products and services that focus on the needs of our customers in drug discovery, life science and industrial markets.

Our umbrella brand:	DWK LIFE SCIENCES DURAN WHEATON KIMBLE
Our product brand:	DURAN
Our borosilicate glass 3.3 brand:	DURAN®

Contact:

Area	**Product Management**
Function	Product Manager Pharma
email	pharma@dwk.com

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DWK Life Sciences – DURAN PURE relevant locations

For DURAN PURE products relevant locations of DWK Life Sciences are located in Mainz (DURAN Produktions GmbH & Co. KG), Wertheim (DURAN Glastechnik GmbH & Co. KG) and Pula (DURAN d.d.). These sites cover the entire value-added chain from glass melting to precision moulding and manufacturing processes.

Wertheim DWK Life Sciences GmbH Otto-Schott-Str. 21 D-97877 Wertheim/Main	Business areas: Sales and Marketing
Wertheim DURAN Glastechnik GmbH & Co. KG Otto-Schott-Str. 21 D-97877 Wertheim/Main	Business areas: Laboratory products for converters, the specialist laboratory trade and the pharmaceutical industry, special industrial products for customer-specific requirements
Mainz DURAN Produktions GmbH & Co. KG Hattenbergstraße. 10 D-55122 Mainz	Business areas: Laboratory products for converters, the specialist laboratory trade and the pharmaceutical industry, articles for the small household goods industry and other industrial applications
Pula DURAN d.d. Mazuraniceva 3 52100 Pula HR-Croatia	Business areas: Laboratory articles for DURAN Produktions GmbH & Co. KG and DURAN Glastechnik GmbH & Co. KG, special industrial products for customer-specific requirements



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Product range of relevant DWK Life Sciences sites

At our locations in Germany and Croatia we produce articles for the following areas: laboratory glass, consumer glass and special industrial glass.



We offer a range of more than 5000 articles in the field of laboratory glass and accessories, and also laboratory products for converters. Those products are produced at our sites in Mainz, Pula and Wertheim.



The Consumer Glass Division develops individually designed products together with its customers, produced at our site in Mainz.



The Special Industrial Glass Division situated at our site in Wertheim, produces more than 3000 customer-specific articles.

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Manufacturer of the Premium lip seal cap made from PFA

The manufacturer of the Premium lip seal cap is a well-known co-operation partner of DWK Life Sciences. Production is carried out in Germany.
The company has worldwide patents and innovative product development. The company is certified according to ISO 9001.
Agreements and Change Control Agreements between DWK Life Sciences and the manufacturer of the Premium lip seal cap GL45 made from PFA plus regular supplier audits ensure the consistently high quality of our products. Details of this manufacturer are available upon signing a Confidentiality Agreement with DWK Life Sciences.

The Premium lip seal cap made from PFA

Thanks to its highly resistant material, the Premium lip seal cap is very suitable for chemically and thermally demanding processes. Due to very high temperature resistance, it is ideal for demanding sterilisation processes such as hot-air or dry-heat sterilisation and depyrogenation up to 260°C.
The materials used comply with FDA / USP / EP and JP guidelines. This makes the Premium lip seal cap particularly suitable for use in the pharmaceutical, chemical and food industries.
The Premium lip seal cap seals bottles tightly and is particularly suitable for storing and transporting sensitive products.

- Made from PFA
- Outstanding temperature resistance from -196 °C to +260 °C
- Ideal for dry-heat sterilisation / depyrogenation
- Very high level of chemical resistance
- Complies with USP Class VI
- No colour additives (leaching of dyes impossible)
- The cap is biocompatible and not cytotoxic

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Tightness test

Twelve bottles are each fitted with the Premium lip seal cap made from PFA GL45. Each bottle is closed 30 times, with a torque application of 3.39 Nm. To decrease the volume, each bottle is lined with a spacer to reduce weight and to ensure a fill level of no less than 5 cm. The empty bottles are weighed. Ten bottles are then filled to 13 mm below the rim with CaCl2. The bottles are immediately closed with a torque of 3.39 Nm and weighed again. Two bottles are used as control specimens. These are filled with glass beads and weighed. All bottles are placed in a desiccator in which is 35 g NaCl for every 100 ml of deionized water. At a storage temperature of 23 ± 2°C, this produces a relative humidity of 75 ± 3%. After 336 ± 1 hour, the bottles are removed from the desiccator and weighed again. To determine the empty volume, five bottles are filled to the rim with deionized water and the volume is measured with a measuring cylinder. The moisture permeation is calculated using the following formula:

Moisture permeation [mg / day x Litre] = *(1000/14xV) x [(TF – TI) – (CF – CI)]*

TF: End weight of bottles tested with CaCl2; **TI:** Start weight of bottles tested with CaCl2; **CF:** Mean end weight of control samples; **CI:** Mean start weight of control samples.

Result

Sample	1	2	3	4	5	6	7	8	9	10
Moisture permeation [mg / day x Litre]	0,3	0,4	0,8	0,4	0,6	0,6	0,6	0,3	0,4	0,4

The tested DURAN PURE bottles and Premium lip seal GL45 screw caps are "tight containers" in accordance with *USP 36 <671> Containers-Performance Testing "Moisture Permeation"*.

Please note that specific safety conditions were maintained during this test.
These results do not give any indication regarding the pressure strength of DURAN® bottles.

Disclaimer:
The party placing a final product in the market is responsible for every deduction and statement based on the above results. It is the responsibility of the said party to decide whether the described tests are adequate to ensure container closure integrity for their respective goods and applications.

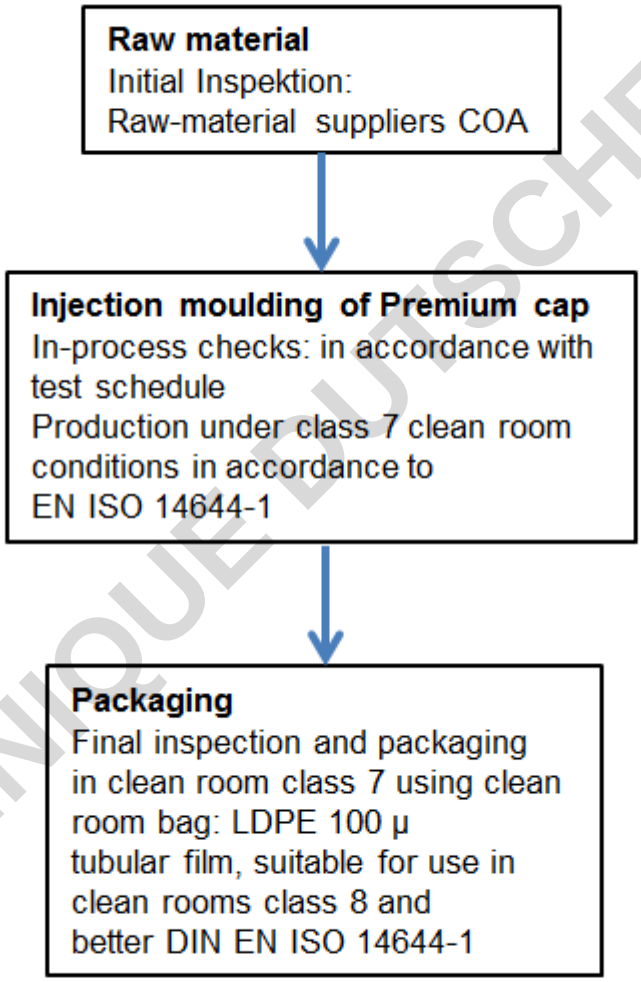
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Sterilisation

The Premium lip seal cap made of PFA is suitable for steam sterilisation (autoclaving) and dry-heat sterilisation for a brief period at 260 degrees Celsius.

Manufacturing process



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Process-related documentation

The manufacturer's production is in accordance with valid specification and drawing.

Our specification contains information on:

- Product
- Physical and chemical properties
- Traceability
- Quality
- Test criteria and tests
- Packaging
- Labelling
- Storage
- Waste disposal

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Lot

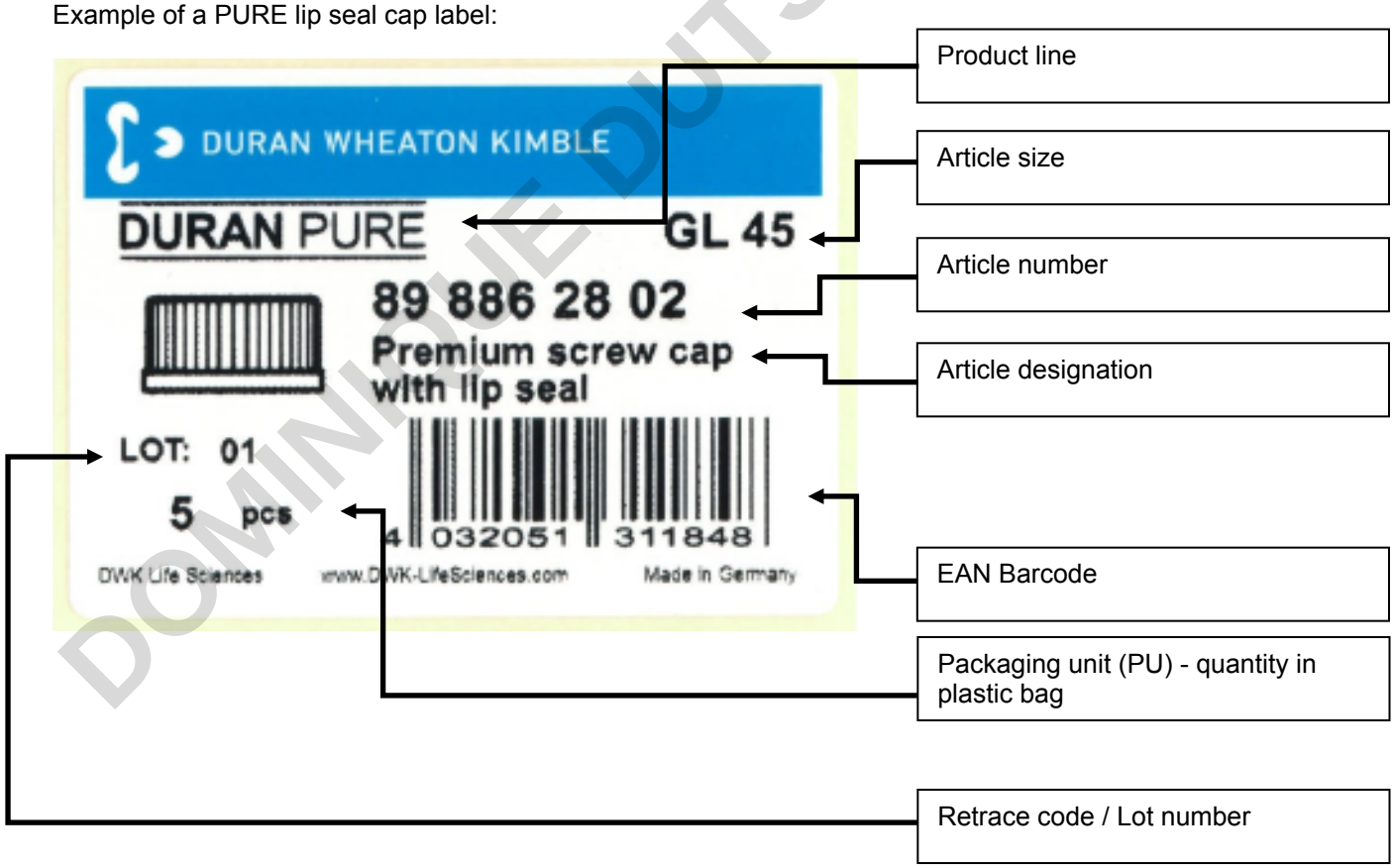
Premium lip seal cap made of PFA

A lot of the Premium lip seal cap made of PFA is defined as the contract-related production quantity that may differ in its quantitative scope depending on the contract quantity on the part of DWK Life Sciences in each case.
A lot number applied to the lid in the production process is used for clear identification of the production unit or the production order and for traceability of the materials used.

The Premium lip seal cap certificate (CoA) contains the following information:

- Article number
- Article designation
- Retrace code / Lot number
- Date of manufacture
- Product attributes
- Test criteria
- Compliance with directives
- Analysis results

Example of a PURE lip seal cap label:



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Quality

The requirement of our customers for our company to develop and manufacture reliable and safe products in accordance with the highest possible international quality standards is at the very centre of our quality policy. In close cooperation with all our staff and with the active involvement of our customers and suppliers, DWK Life Sciences has established a quality management system that conforms to DIN EN ISO 9001 and which is integrated into daily practice.

This quality management system is the foundation for all the processes that our products have to go through: from the customer's initial enquiry, through to order processing and delivery and up to customer feedback. We value the success of DURAN® products as a sign of confidence from our customers in our quality system, in our logistics and in our service. Moreover, we are constantly working on improving our performance by assessment of the status quo and from it deriving new, ambitious goals, which we want to attain through process-orientated thinking, planning and action.

In everything we do, customer and staff satisfaction, as well as adherence to the principles of environmental sustainability, are the important criteria that we constantly measure and aim to improve upon.

Safety and environmental protection

Human safety and protection of the environment are important goals for our company. To achieve this, we are constantly working on the development of more environmentally sustainable products and manufacturing processes while ensuring we use resources in a sparing and responsible manner and set high standards for the safe operation of our plant.

DWK Life Sciences is committed to responsible and fair behavior towards society and the environment. Legislative guidelines and official ordinance are considered a minimum requirement. In our daily operations we go well beyond this minimum.

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Transport packaging

Transport packaging for Premium lip seal cap made of PFA

The Premium lip seal cap is packed into clean room bag: LDPE 100 µ tubular film, suitable for use in clean rooms class 8 and better DIN EN ISO 14644-1 (5 pieces per bag) and labelled.

Transport packaging label

Example of DURAN PURE label is included on page 10.

Sales

DWK Life Sciences is represented all over the world through its co-operation with SCHOTT Sales Offices and a wide dealership network. The Mainz location has a high-rack warehouse with approx. 30,000 pallet spaces. The worldwide main dealership system provides optimum local deliverability.

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Validity

This qualification documentation is valid from the date of release and supersedes all prior versions.

Qualification documentation to confirm compliance of our products

We hereby confirm that we produce and test our products based on the hereinafter mentioned specifications, standards and guidelines.

Appendix:

Premium lip seal cap Specification (including MSDS and Conformity Statements)
Premium lip seal cap Drawing

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