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Specification Membrane screw cap made from PP

1. Table of revision

Rev.-Nr.	change
001	New specification
002	Update Section 7. – Lebensmittelechtheit / Food Grade
003	Update section 6 product traceability, explanation packing date code

2. Product descpription

Product name	DURAN® Sterile-Venting Membrane Screw Caps in three thread sizes: GL 25, 32 and 45
SAP Art.-Nr.	291181307 GL 25 291181907 GL 32 291182809 GL 45
Product description and application	• Pressure equalisation during steam sterilisation / autoclaving of media or buffers in DURAN® GL lab bottles • Sterile gas exchange for aerobic microbial, shaker and suspension cell cultures in DURAN® bottles • Short-term storage of sterilised media in DURAN® bottles • Storage of gas generating materials in DURAN® bottles **Note:** • Suitable for use with DURAN® GL bottles in sizes from 10 ml up to 3500 ml • For DURAN® GL 45 bottles that are 5 Litres or larger, we recommend the use of article number: 292612607 (DURAN® 1-port stainless steel Connection Cap System GL 45) together with a suitable sterile air venting capsule filter.

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3. Product properties

Drawing reference	291181307 D361018-GZA-0GL25-A 291181907 D360921-GZA-0GL32-A 291182809 D161655-GZA-0GL45-B
Material description	Blue polypropylene screw caps with ultrasonically welded Expanded PTFE membrane. For plastic cap see: „Spezifikation Schraubverschluss und Ausgießring aus Polypropylen (PP) / Specification screw cap and pouring ring made of Polypropylene (PP) DG ML 0102B“
Key parameters	291181307 1x 5.5 mm vent hole 291181907 1x 8.0 mm vent hole 291182809 3x 9.0 mm vent holes
Material	Hydrophobic expanded PTFE with polypropylene mesh support PF-X02W
Thickness	340 +/- 100 microns
Pore size	0.2 microns
Water entry Pressure (60 seconds)	130 - 235 kPa
Air flow	3.8 - 10.3 Litres per minute per cm^2 at 1 bar

4. Colour

Colour Description	**Pantone Colour Reference**
Cap body	Dark blue
Membrane Surface colour	White

5. Packaging and labeling

Number of pieces per pack	5
Packaging visible appearance	Heat sealed Clear plastic bag with self adhesive product label

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6. Product Traceability

Type	Code	Format
Manufacturing Retrace Code	None	**None**
Packaging Date Code	See Packaging Code	MM.YY (+20)

7. Product Certification and Conformance

Conformance	Product compliant?	Relevant Legislation
Lebensmittelechtheit / Food Grade	Yes (for PTFE membrane)	FDA CFR 177.1550 Regulation (EU) No. 10/2011
BSE / TSE	Yes (for PTFE membrane)	Animal product free statement BSE
USP / EP / JP	Yes (for PTFE membrane)	USP <88> 121 °C Class VI
RoHS	Yes (for PTFE membrane)	RoHS Directive 2011/65/EU
REACH	Yes (for PTFE membrane)	REACH Regulation (EU) 1907/2006

8. Temperature Resistance

Recommended usage and temperature range	0 °C to + 140 °C
Autoclaveability	121 °C (20 minutes) or 134 °C (3 minutes) Replacement of the DURAN® membrane cap is recommended after 3 to 5 autoclave cycles due to durability, or if the membrane becomes damaged or contaminated

9. Cleaning Recommendations

Type of cleaning	Recommended yes / no	Description
Hand washing process	No	Not applicable
Automated washing process	No	Not applicable

10. Recommended Storage Conditions

Store in original packaging under normal conditions in accordance with standard climatic conditions +23 °C and 50% relative humidity in accordance with ISO 554:1976.
Protect from humidity, large temperature fluctuations and direct sunlight.

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Avoid exposing plastic components to sunlight and other sources of ultra-violet light (UV).

11. Waste Disposal Recommendations

Used or unused articles cannot be returned to the manufacturer.

European Waste Catalogue	EWC code: 19 12 04 plastic and rubber, Commission Decision 2000/532/EC
Conformance with packaging waste regulations	CONEG "Toxics in Packaging" Model Legislation, rev. 2008 Directive 94/62/EC (Packaging and packaging waste -PPW) and related EN13428 and CR13695- Sum of Cd, Cr, Hg and Pb < 100 ppm

12. Quality management

The target is to manufacture a constant, previously agreed to standard of quality, to secure this standard with quality inspections as well as to take quick corrective measures in case of any deviations in order to be able to carry out production operations within permissible limits on a stable basis.

In order to determine any deviations or shifts of quality that may be detected, the inspection is integrated in the manufacturing process (worker self-inspections).
The proper relationships of inspection range and inspection criteria are guaranteed by means of defined inspection specifications.

13. Complaint management

In case of complaints, please contact our service team by using the following email address: complaint@dwk-lifesciences.com
Complaints must refer to the quality limit values or properties stated in the DWK Life Sciences specification. Post-processing, sorting, scrapping or returning potentially faulty items may entail costs; it is essential that any actions are agreed upon in advance between the customer and DWK Life Sciences.

14. Scope

This product specification is the basis for quality considerations at DWK Life Sciences and at its customers/suppliers. It applies to all products produced and supplied since this specification came into effect.

15. Validity

This specification replaces all previous specifications.