

Herstellereklärung	Manufacturer Declaration
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Kontaktmaterialien für Lebensmittel- und Pharma-Anwendungen	Contact materials for food and beverage and pharmaceutical applications
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Hersteller / Manufacturer: **Bürkert Werke GmbH & Co. KG**
Christian-Bürkert-Straße 13-17
74653 Ingelfingen, Germany
www.burkert.com

Hiermit erklären wir, dass die nachfolgend aufgeführten Produkte den genannten Bestimmungen entsprechen.

We hereby declare that the products listed below comply with the stated regulations.

Typ / Type (Geräteschlüssel / product specification key):

- | | |
|---|---|
| <p>2031-**-****-①-②-****-** ③
 2032-**-****-①-**-②-****-****-** ③
 2033-**-****-①-**-②-****-****-** ③</p> <p>2034-**-**-**-**-②-①-****-****-**** ③</p> <p>2036-****-①-②-****-****-****-**** ③</p> <p>2731-**-****-①-②-****-**-**-**** ③</p> <p>2103-**-****-①-②-****-**-****-**** ③
 2104-**-****-①-②-****-****-****-**** ③
 2105-**-****-①-②-****-****-****-**** ③</p> <p>2063-**-****-①-②-****-**-****-**** ③
 2064-**-****-①-②-****-****-****-**** ③
 2065-**-****-①-②-****-****-****-**** ③</p> | <p>2933-**-****-①-②-****-****-**-****-** ③
 2934-**-****-①-②-****-****-****-****-** ③
 2935-**-****-①-②-****-****-****-****-** ③
 2973-**-****-①-②-****-****-**-****-** ③
 2974-**-****-①-②-****-****-****-****-** ③
 2975-**-****-①-②-****-****-****-****-** ③</p> <p>3323-**-****-①-②-****-**-****-****-**** ③
 3324-**-****-①-②-****-****-****-****-**** ③
 3325-**-****-①-②-****-****-****-****-**** ③</p> <p>3363-**-****-①-②-****-**-****-****-**** ③
 3364-**-****-①-②-****-****-****-****-**** ③
 3365-**-****-①-②-****-****-****-****-**** ③</p> <p>SV01-****-****-①-**-****-****-****-**** ③
 SV02-****-**-****-①-**-****-****-**** ③</p> |
|---|---|

① Dichtwerkstoff / Seal material (DWST): **AD, EA, P5, EU, P6, ER, EK**

② Werkstoff / material (WKST): **VP, VS, VG, VH, VI, PD**

③ Gilt nur in Verbindung mit variablem Code in Abhängigkeit des Dichtwerkstoffs (DWST) bzw. dem Werkstoff (WKST) / Only valid in combination with variable code depending on the sealing material (DWST) or the material (WKST):
PL01, PL02, PL03, PL04, PL10, PL11, PL12

Variable(r) Code	Medienberührende Materialien erfüllen folgende Anforderungen:	Materials in contact with the medium fulfill the following requirements:
PL02 oder / or PL03	FDA (Food and Drug Administration, USA) CFR 21 (Code of Federal Regulations) AD: Paragraph 177.2600 Positivliste für wässrige Lebensmittel EA, EU, ER: Paragraph 177.1550 P5 & P6: Paragraph 177.1550 (a) bis (e)	FDA (Food and Drug Administration, USA) CFR 21 (Code of Federal Regulations) AD: Paragraph 177.2600 Positive list for aqueous foods EA, EU, ER: Paragraph 177.1550 P5 & P6: Paragraph 177.1550 (a) to (e)
PL03	FDA (Food and Drug Administration, USA) CFR 21 (Code of Federal Regulations) PD: Paragraph 177.2510 nur für Granulat EK: Paragraph 177.1550 (a)(1)	FDA (Food and Drug Administration, USA) CFR 21 (Code of Federal Regulations) PD: Paragraph 177.2510 only for granulate EK: Paragraph 177.1550 (a)(1)

Die Sicherheits- und Einbauhinweise der mitgelieferten Produktdokumentation sind zu beachten

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<p>PL01 oder / or PL02</p>	<p>Verordnung EG 1935/2004 Die verwendeten Werkstoffe und Rohstoffe entsprechen dieser Verordnung und der Verordnung EU 10/2011 mit Änderungen bis EU 2025/351.</p> <p>AD <u>Prüfparameter:</u> 2h / 100°C / 20% Ethanol 1kg (Mehrfachgebrauch) Durchfluss von mind. 0,00663kg pro Schaltung</p> <p>EA: <u>Prüfparameter:</u> 2h / 140°C / 20% Ethanol 1kg 2h / 100°C / 95% Ethanol 1kg</p> <p><u>Spezifische Migrationslimits:</u> TFE: SML 0,05 mg/kg</p> <p>P5: <u>Prüfparameter:</u> 4h / 100°C / 10% Ethanol (Mehrfachgebrauch) 4h / 100°C / 3% Essigsäure (Mehrfachgebrauch) 2h / 175°C / Olivenöl (Mehrfachgebrauch) O/V = 0,01dm² / ml</p> <p><u>Spezifische Migrationslimits:</u> TFE: SML 0,05 mg/kg</p> <p>EU: <u>Prüfparameter:</u> 2h / 140°C / 20% Ethanol 1kg 2h / 100°C / 95% Ethanol 1kg</p> <p><u>Spezifische Migrationslimits:</u> TFE: SML 0,05 mg/kg PPVE: SML 0,05 mg/kg</p> <p>P6: <u>Prüfparameter:</u> 4h / 100°C / 10% Ethanol (Mehrfachgebrauch) 4h / 100°C / 3% Essigsäure (Mehrfachgebrauch) 2h / 175°C / Olivenöl (Mehrfachgebrauch) O/V = 0,01dm² / ml</p> <p><u>Spezifische Migrationslimits:</u> TFE: SML 0,05 mg/kg PPVE: SML 0,05 mg/kg</p> <p>ER: <u>Prüfparameter:</u> 2h / 100°C / 20% Ethanol 1kg</p> <p><u>Verwendungsbedingungen:</u> Die Verwendungsbedingungen ergeben sich aus den genannten Prüfparametern.</p> <p><u>Oberflächen/Volumen-Verhältnis:</u> Wenn nicht anders angegeben wurde, berücksichtigen wir zur Bewertung der Konformität das reale Oberflächen/Volumen-Verhältnis, welches strenger ist als 6 dm²/1kg (EU-Würfel).</p>	<p>Regulation EC 1935/2004 The materials and raw materials used comply with this Regulation and the Regulation EU 10/2011 and subsequent amendments up to EU 2025/351.</p> <p>AD <u>Testing parameter:</u> 2h / 100°C / 20% Ethanol 1kg (repeated use) Flow of at least 0.00663kg per switching</p> <p>EA: <u>Testing parameter:</u> 2h / 140°C / 20% Ethanol 1kg 2h / 100°C / 95% Ethanol 1kg</p> <p><u>Specific migration limits:</u> TFE: SML 0,05 mg/kg</p> <p>P5: <u>Testing parameter:</u> 4h / 100°C / 10% Ethanol (repeated use) 4h / 100°C / 3% Acetic Acid (repeated use) 2h / 175°C / Olive Oil (repeated use) S/V = 0,01dm² / ml</p> <p><u>Specific migration limits:</u> TFE: SML 0,05 mg/kg</p> <p>EU: <u>Testing parameter:</u> 2h / 140°C / 20% Ethanol 1kg 2h / 100°C / 95% Ethanol 1kg</p> <p><u>Specific migration limits:</u> TFE: SML 0,05 mg/kg PPVE: SML 0,05 mg/kg</p> <p>P6: <u>Testing parameter:</u> 4h / 100°C / 10% Ethanol (repeated use) 4h / 100°C / 3% Acetic Acid (repeated use) 2h / 175°C / Olive Oil (repeated use) S/V = 0,01dm² / ml</p> <p><u>Specific migration limits:</u> TFE: SML 0,05 mg/kg PPVE: SML 0,05 mg/kg</p> <p>ER: <u>Testing parameter:</u> 2h / 100°C / 20% Ethanol 1kg</p> <p><u>Conditions of use:</u> The conditions of use result from the mentioned test parameters.</p> <p><u>Surface/volume ratio:</u> Unless otherwise stated, we consider the actual surface/volume ratio to assess conformity, which is stricter than 6 dm²/1kg (EU cube).</p>
	<p>PL04</p>	<p>USP (US Pharmacopeia)</p> <p>AD, EA, P5, EU, P6, ER, EK: Kapitel <87> in vitro Kapitel <88> in vivo Class VI (121°C/1h)</p>

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China GB Standard

P5:

GB 4806.1-2016
GB 4806.7-2023 (repeated use)
GB9685-2016
TFE: SML 0,05 mg/kg and Overall migration 10 mg/dm²
S/V: 6 dm² / 1L

Test Item	Limit	Assessment	Test Method
Sensory	Comply	Pass	GB 4806.7-2023
Overall migration 4% Acetic Acid, 2h, 100°C	≤ 10	Pass	GB 31604.8-2021
Overall migration 10% Ethanol, 2h, 100°C	≤ 10	Pass	GB 31604.8-2021
Overall migration 95% Ethanol, 6h, 60°C	≤ 10	Pass	GB 31604.8-2021
Overall migration Isooctane, 2h, 60°C	≤ 10	Pass	GB 31604.8-2021
Consumption of potassium permanganate water, 60°C, 0,5h, 3rd time	≤ 10	Pass	GB 31604.2-2016
Heavy metal (as Pb) 4% acetic acid, 2h, 60°C	≤ 1	Pass	GB 31604.9-2016 1st method
Potassium permanganate consumption water, 2h, 60°C	≤ 10	Pass	GB 31604.2-2016
Decolourising 4% Acetic Acid, 10% Ethanol, Vegetable Oil	Negative	Pass	GB 31604.7-2023

P6:

GB 4806.1-2016
GB 4806.7-2023 (repeated use)
GB9685-2016
TFE: SML 0,05 mg/kg and Overall migration 10 mg/dm²
PPVE: SML 0,05 mg/kg and Overall migration 10 mg/dm²
S/V: 6 dm² / 1L

Test Item	Limit	Assessment	Test Method
Sensory	Comply	Pass	GB 4806.7-2023
Overall migration 4% Acetic Acid, 2h, 100°C	≤ 10	Pass	GB 31604.8-2021
Overall migration 10% Ethanol, 2h, 100°C	≤ 10	Pass	GB 31604.8-2021
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Overall migration Isooctane, 2h, 60°C	≤ 10	Pass	GB 31604.8-2021
Consumption of potassium permanganate water, 60°C, 0,5h, 3rd time	≤ 10	Pass	GB 31604.2-2016
Heavy metal (as Pb) 4% acetic acid, 2h, 60°C	≤ 1	Pass	GB 31604.9-2016 1st method
Potassium permanganate consumption water, 2h, 60°C	≤ 10	Pass	GB 31604.2-2016

VP, VS, VG, VH, VI:

GB 4806.1-2016
GB 4806.9-2023
S/V: 6 dm² / 1L

Test Item	Limit	Assessment	Test Method
Content of metal impurities	≤ 0.01	Pass	Q/DPTC-ZL-3-F-348
Sensory	Comply	Pass	GB 4806.9-2023
Migration indexes of metal impurities 5g/L citric acid, 100°C, 2h, 3 rd time	varying	Pass	GB 31604.49-2023 2 nd chapter 1 st method
Migration indexes of alloy components 5g/L citric acid, 100°C, 2h, 3 rd time	varying	Pass	GB 31604.49-2023 2 nd chapter 1 st method

**PL10
oder / or
PL12**

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PL10 oder / or PL12	<p>China GB Standard</p> <p>AD: GB 4806.1-2016 GB 4806.11-2023 (repeated use) S/V: 0,0868 dm² / 1L</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Test Item</th> <th>Limit</th> <th>Assessment</th> <th>Test Method</th> </tr> </thead> <tbody> <tr> <td>Sensory</td> <td>Comply</td> <td>Pass</td> <td>GB 4806.11-2023</td> </tr> <tr> <td>Overall migration 10% Ethanol, 4h, 3rd time</td> <td>≤ 10</td> <td>Pass</td> <td>GB 31604.8-2021</td> </tr> <tr> <td>Consumption of potassium permanganate water, 60°C, 0,5h, 3rd time</td> <td>≤ 10</td> <td>Pass</td> <td>GB 31604.2-2016</td> </tr> <tr> <td>Heavy metal (as Pb) 4% acetic acid, 60°C, 0,5h 1st time</td> <td>≤ 1</td> <td>Pass</td> <td>GB 31604.9-2016 1st method</td> </tr> <tr> <td>Sum of primary aromatic amines released 10% Ethanol, 8h, 1st time</td> <td>< 0,01 mg/kg</td> <td>Pass</td> <td>GB 31604.52-2021</td> </tr> </tbody> </table>		Test Item	Limit	Assessment	Test Method	Sensory	Comply	Pass	GB 4806.11-2023	Overall migration 10% Ethanol, 4h, 3rd time	≤ 10	Pass	GB 31604.8-2021	Consumption of potassium permanganate water, 60°C, 0,5h, 3rd time	≤ 10	Pass	GB 31604.2-2016	Heavy metal (as Pb) 4% acetic acid, 60°C, 0,5h 1st time	≤ 1	Pass	GB 31604.9-2016 1st method	Sum of primary aromatic amines released 10% Ethanol, 8h, 1st time	< 0,01 mg/kg	Pass	GB 31604.52-2021				
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PL10	<p>China GB Standard</p> <p>EA, EU, ER: GB 4806.1-2016 GB 4806.7-2023 S/V: 6 dm² / 1 L</p> <table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th>Test Item</th> <th>Limit</th> <th>Assessment</th> <th>Test Method</th> </tr> </thead> <tbody> <tr> <td>Sensory</td> <td>Comply</td> <td>Pass</td> <td>GB 4806.7-2023</td> </tr> <tr> <td>Overall migration 20% Ethanol, 4h, 3rd time</td> <td>≤ 10</td> <td>Pass</td> <td>GB 31604.8-2021</td> </tr> <tr> <td>Consumption of potassium permanganate water, 60°C, 2h, 1st time</td> <td>≤ 10</td> <td>Pass</td> <td>GB 31604.2-2016</td> </tr> <tr> <td>Heavy metal (as Pb) 4% acetic acid, 60°C, 2h 1st time</td> <td>≤ 1</td> <td>Pass</td> <td>GB 31604.9-2016 1st method</td> </tr> <tr> <td>Sum of primary aromatic amines released 20% Ethanol, reflux temperature, 8h, 1st time</td> <td>< 0,01 mg/kg</td> <td>Pass</td> <td>GB 31604.52-2021</td> </tr> <tr> <td>Decolor test</td> <td>Negative</td> <td>Pass</td> <td>GB 31604.7-2023</td> </tr> </tbody> </table>		Test Item	Limit	Assessment	Test Method	Sensory	Comply	Pass	GB 4806.7-2023	Overall migration 20% Ethanol, 4h, 3rd time	≤ 10	Pass	GB 31604.8-2021	Consumption of potassium permanganate water, 60°C, 2h, 1st time	≤ 10	Pass	GB 31604.2-2016	Heavy metal (as Pb) 4% acetic acid, 60°C, 2h 1st time	≤ 1	Pass	GB 31604.9-2016 1st method	Sum of primary aromatic amines released 20% Ethanol, reflux temperature, 8h, 1st time	< 0,01 mg/kg	Pass	GB 31604.52-2021	Decolor test	Negative	Pass	GB 31604.7-2023
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Sum of primary aromatic amines released 20% Ethanol, reflux temperature, 8h, 1st time	< 0,01 mg/kg	Pass	GB 31604.52-2021																											
Decolor test	Negative	Pass	GB 31604.7-2023																											
PL11 oder / or PL12	<p>Japan MHLW Positiv Liste (Ministry of Health, Labour and Welfare)</p> <p>P5, P6, ER: CAS No. 9002-84-0 Referenznr.: 864</p>	<p>Japan MHLW Positive List (Ministry of Health, Labour and Welfare)</p> <p>P5, P6, ER: CAS No. 9002-84-0 reference no.: 864</p>																												
PL01	<p>VP, VS, VG, VH, VI: Die verwendeten Metalle entsprechen den Anforderungen aus „Metals and alloys...“ 2024.</p> <p><u>Prüfparameter:</u> 2h / 130°C / 0,5% Zitronensäure 1kg</p>	<p>VP, VS, VG, VH, VI: The metals used comply with the requirements of „Metals and alloys...“ 2024.</p> <p><u>Testing parameter:</u> 2h / 130°C / 0,5% Citric acid 1kg</p>																												

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PL01 oder / or PL02 oder / or PL03 oder / or PL04 oder / or PL10 oder / or PL11 oder / or PL12	AD, EA, P5, EU, P6, ER, PD: ADI Das Material enthält keine Materialien tierischen Ursprungs als Rezepturbestandteil.	AD, EA, P5, EU, P6, ER, PD: ADI The material does not contain any materials of animal origin as part of the recipe.
	AD, EA, P5, EU, P6, ER, PD: Phthalate Das Material enthält keine Phthalate als Rezepturbestandteil.	AD, EA, P5, EU, P6, ER, PD: Phthalates The material does not contain any phthalates as part of the recipe.
	AD, EA, P5, P6, ER: Lebensmittelallergene Das Material enthält keine Allergene als Rezepturbestandteil gemäß EU 1169/2011 Anhang II.	AD, EA, P5, P6, ER: Food Allergens The material does not contain any allergens as part of the recipe according to EU 1169/2011 Annex II.
	AD, EA, P5, EU, P6, ER, PD: Nitrosamine Das Material enthält keine Nitrosamine als Rezepturbestandteil.	AD, EA, P5, EU, P6, ER, PD: Nitrosamines The material does not contain any nitrosamines as part of the recipe.
	AD: Vernetzungsart Das Material ist peroxidisch vernetzt.	AD: Crosslinking type The material is peroxide-crosslinked.
	AD, EA, P5, EU, P6, ER, EK: Die medienberührenden Bauteile der unten genannten Produkte sind nicht aus Naturkautschuk hergestellt und wurden ohne die beabsichtigte Verwendung von Naturkautschuk (Natural Rubber, NR/NRL) gefertigt.	AD, EA, P5, EU, P6, ER, EK: The wetted parts of the products listed below are not made with natural rubber latex and were manufactured without the intentional use of natural rubber (NR/NRL).

Zusätzliche Hinweise:

- Basierend auf unserem Qualitätsmanagementsystem nach ISO 9001 bestätigen wir, dass unsere Produkte nach bestem Wissen und Gewissen und nach dem aktuellen Stand der Technik hergestellt werden (in Anlehnung an die Richtlinie EG 2023/2006 für gute Herstellungspraxis GMP).
- Die Bedienungsanleitung vom Ventil ist zu beachten.
- Das Produkt darf nicht außerhalb der festgelegten Grenzen betrieben werden.
- Es liegt in der Verantwortung des Kunden zu entscheiden, ob die beabsichtigte Anwendung die relevanten Vorgaben erfüllt.

Additional information:

- Based on our Quality Management System according to ISO 9001 we declare that our products are manufactured to the best of our knowledge and belief and according to the current state of the art (referring to the Directive EC 2023/2006 for good manufacturing practices GMP).
- Observe the instruction manual of the valve.
- Do not operate the product outside the described limits.
- It is the responsibility of the client to determine whether the intended application complies with relevant requirements.

Ingelfingen, 17. Februar 2026

i.A. 
 Stefan Taubenberger
 Product Compliance