# DECLARATION OF CONFORMITY

**Company:**

**Supplier:** MODU Valves A/S, Ferrarivej 12, 7100 Vejle, Denmark

***Manufacturer:*** *Transworld Steel Enterprise Co., Ltd., No. 34, 14th Road, Da-Li Industrial Park, Da-Li City, Taichung Hsien, 412, Taiwan*

*hereby declare, that our Stainless Steel ball valves:*

***Products*:**

- *Three piece Stainless Steel ball valves* MODU 77, MODU 83, MODU 88
- *Two piece Stainless Steel ball valves* MODU 22, MODU 90D, MODU 99
- *Multiport Stainless Steel ball valves* MODU 33, MODU 39M

***combined / mounted with parts (seat rings, joint gaskets etc.) manufactured from following materials:***

- PTFE
- CPTFE (*25% Carbon Powder filled PTFE)*

***are complying with, and in full conformity with, following EU regulations:***

- *EC-Regulation* Nr. 1935/2004
- *EC-Regulation* Nr. 2023/2006
- *EC-Regulation* Nr. 10/2011

***as well as complying with, and in full conformity with, following Danish regulations:***

- BEK Nr. 681/2020 (replacement for BEK Nr. 1248/2018)
- BEK Nr. 1520/2022 (replacement for BEK Nr. 1428/2017)

***Scope of use:***

The above mentioned valve types may be used for all type of foods.

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**Test conditions and results for PTFE and CPTFE:**

| Type of analysis | Conclusion | Regulation or protocol |
|---|---|---|
| Overall Migration (repeated use) | Pass | (EU) No 10/2011 |
| Content Analysis + specific migration calculation | Pass | (EU) No 10/2011 |

**Applied Test Methods**

***General Test References***

| Method | Parameter | Analysis principle | LOD | Um(%) |
|---|---|---|---|---|
| External subcontractor *¤[1] | Content analysis of Tetrafluoroethylene (TFE) | HS-GC-MS/FID | 0.05 mg/kg | - |
| Calculation * | Tetrafluoroethylene (TFE) | Worst-case calculation of the specific migration based on the content analysis of TFE | - | - |
| DIN EN 1186-3:2022-10 mod.[2] | Preparation for migration | Exposure to 3% acetic acid by immersion | - | - |
| DIN EN 1186-3:2022-10 mod.[2] | Overall migration into 3% acetic acid | Gravimetry | 2 mg/dm² | 20% |
| DIN EN 1186-3:2022-10 mod.[2] | Preparation for migration | Exposure to 10% ethanol by immersion | - | - |
| DIN EN 1186-3:2022-10 mod.[2] | Overall migration into 10% ethanol | Gravimetry | 2 mg/dm² | 20% |
| DIN EN 1186-3:2022-10 mod.[2] | Preparation for migration | Exposure to olive oil by immersion | - | - |
| DIN EN 1186-2:2022-10 (mod: autom. Derivatization )[2] | Overall migration into olive oil | Gravimetry | 2 mg/dm² | 20% |

**Test Conditions**

| Simulant | Technique | Area exposed [dm²] | Volume (Simulant) [mL] | Migration Conditions |
|---|---|---|---|---|
| 3% acetic acid | Immersion | 1.8 | 180 | 3 x 24 Hours at 100 °C (repeated use) |
| 10% ethanol | Immersion | 1.8 | 180 | 3 x 4 Hours at 90 ° C (repeated use) |
| Olive oil | Immersion | 0.9 | 90 | 3 x 2 Hours at 175 ° C (repeated use) |

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**Overall migration**

| Simulant | Single determinations | | | Average | OML value |
|---|---|---|---|---|---|
| | [mg/dm² ] | [mg/dm² ] | [mg/dm² ] | [mg/dm² ] | [mg/dm²] |
| **10% ethanol (1. migration)** | < 2 | < 2 | < 2 | < 2 | - |
| **10% ethanol (2. migration)** | < 2 | < 2 | < 2 | < 2 | - |
| **10% ethanol (3. migration)** | < 2 | < 2 | < 2 | < 2 | 10 |
| **3% acetic acid (1. migration)** | < 2 | < 2 | < 2 | < 2 | - |
| **3% acetic acid (2. migration)** | < 2 | < 2 | < 2 | < 2 | - |
| **3% acetic acid (3. migration)** | < 2 | < 2 | < 2 | < 2 | 10 |
| **Olive oil (1. migration) – M1** | 3.0 | 2.7 | 2.5 | 3.0 | - |
| **Olive oil (2. migration) – M2-M1** | < 2 | < 2 | < 2 | < 2 | - |
| **Olive oil (3. migration) – M3-M2** | < 2 | < 2 | < 2 | < 2 | 10 |

**Content analysis and worst-case calculation of migration**

| Parameter | CAS No. | Result | Limit value |
|---|---|---|---|
| | | [mg/kg] | [mg/kg] |
| **Tetrafluoroethylene (TFE) (content)** | 116-14-3 | < 0.05 | - |
| **Tetrafluoroethylene (TFE) (Worst-case calculation of migration)** | 116-14-3 | < 0.05 # | 0.05 |

# Based on cube assumption (6 dm² per kg food)

**Summary and Evaluation of the Results**

The results for overall migration **are below** the threshold value of 10 mg/dm² and the migration did not increase from the 1st to the 2nd and from the 2nd to the 3rd migration.

The results for the specific migration calculation of TFE **are below** the limit value.

Consequently, the product tested **complies** with the requirements for in Commission Regulation (EU) No 10/2011 with amendments up to and including Commission Regulation (EU) 2020/1245 on plastic materials and articles intended for **repeated use** contact with food for the above mentioned test conditions.

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**Test conditions and results for Metal parts:**

| Type of analysis | Conclusion | Regulation or protocol |
|---|---|---|
| Specific release of metals | Pass | CM/Res(2013)9 |

Full details based on the testing and direct comparison with limit values are available in the following pages

**Applied Test Methods**

***General Test References***

| Method | Parameter | Analysis principle | LOD | Um(%) |
|---|---|---|---|---|
| Internal method *[1] | Preparation for migration | Exposure to 0.5% citric acid by filling | - | - |
| Internal method *[1] | Metals | ICP-MS | 0.0001 - 5 mg/kg | 30% |

**Test Conditions**

| Simulant | Technique | Area exposed [dm²] | Volume (Simulant) [mL] | Migration Conditions |
|---|---|---|---|---|
| 0.5% citric acid | Filling | 0.25 | 10 | 3 x 24 Hours at 100 °C (repeated use) |

**Results**

***Specific Release of Metals – 1st + 2nd migration***

| Parameter | CAS No. | Food Simulant | 1. + 2. migration [mg/kg] | 7 x SRL value* [mg/kg] |
|---|---|---|---|---|
| **Aluminium *** | 7429-50-5 | 0.5% citric acid | 0.48 | 35 |
| **Antimony *** | 7440-36-0 | 0.5% citric acid | < 0.02 | 0.28 (Transitional SRL = 1.4)** |
| **Arsenic *** | 7440-38-2 | 0.5% citric acid | < 0.002 | 0.014 (Transitional SRL = 0.07)** |
| **Barium *** | 7440-39-3 | 0.5% citric acid | 0.14 | 8.4 |
| **Beryllium *** | 7440-41-7 | 0.5% citric acid | < 0.002 | 0.07 (Transitional SRL = 0.35)** |
| **Cadmium *** | 7440-43-9 | 0.5% citric acid | < 0.002 | 0.0035 (Transitional SRL = 0.14)** |
| **Chromium *** | 7440-47-3 | 0.5% citric acid | 1.2 | 1.75 (Transitional SRL = 7.0)** |
| **Cobalt *** | 7440-48-4 | 0.5% citric acid | 0.043 | 0.14 (Transitional SRL = 0.7)** |
| **Copper *** | 7440-50-8 | 0.5% citric acid | < 0.2 | 28 |
| **Iron *** | 7439-89-6 | 0.5% citric acid | 17 | 280 |
| **Lead *** | 7439-92-1 | 0.5% citric acid | 0.070 | 0.070 (Transitional SRL = 0.28)** |

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| | | | | |
|---|---|---|---|---|
| **Lithium *** | 7439-93-2 | 0.5% citric acid | < 0.002 | 0.336 |
| **Magnesium *** | 7439-95-4 | 0.5% citric acid | 0.24 | - |
| **Manganese *** | 7439-96-5 | 0.5% citric acid | 1.0 | 12.6 |
| **Mercury *** | 7439-97-6 | 0.5% citric acid | < 0.0004 | 0.021 (Transitional SRL = 0.105)** |
| **Molybdenum *** | 7439-98-7 | 0.5% citric acid | 0.13 | 0.84 (Transitional SRL = 4.2)** |
| **Nickel *** | 7440-02-0 | 0.5% citric acid | 0.37 | 0.98 (Transitional SRL = 4.9)** |
| **Silver *** | 7440-22-4 | 0.5% citric acid | < 0.02 | 0.56 |
| **Thallium *** | 7440-28-0 | 0.5% citric acid | < 0.0002 | 0.0007 (Transitional SRL = 0.0035)** |
| **Tin *** | 7440-31-5 | 0.5% citric acid | < 0.02 | 700 |
| **Titanium *** | 7440-32-6 | 0.5% citric acid | < 0.2 | - |
| **Vanadium *** | 7440-62-2 | 0.5% citric acid | 0.0085 | 0.07 (Transitional SRL = 0.35)** |
| **Zinc *** | 7440-66-6 | 0.5% citric acid | 0.56 | 35 |

* Limit values from the EU practical guideline on metals and alloys used in food contact materials and articles (CM/Res(2013)9
** Transitional limit values were communicated in a letter from "Department of Biological Standardisation, OMCL Network & HealthCare (DBO) Consumer Health Protection" to the national authorities on November 18, 2013. These limit values will be reconsidered after 3 years. To date the transitional SRL has not been reconsidered by the authorities yet.

***Specific Release of Metals – 3rd migration***

| **Parameter** | **CAS No.** | **Food Simulant** | **3. migration** [mg/kg] | **SRL value*** [mg/kg] |
|---|---|---|---|---|
| **Aluminium *** | 7429-50-5 | 0.5% citric acid | 0.20 | 5 |
| **Antimony *** | 7440-36-0 | 0.5% citric acid | < 0.01 | 0.04 (Transitional SRL = 0.2)** |
| **Arsenic *** | 7440-38-2 | 0.5% citric acid | < 0.001 | 0.002 (Transitional SRL = 0.01)** |
| **Barium *** | 7440-39-3 | 0.5% citric acid | < 0.01 | 1.2 |
| **Beryllium *** | 7440-41-7 | 0.5% citric acid | < 0.001 | 0.01 (Transitional SRL = 0.05)** |
| **Cadmium *** | 7440-43-9 | 0.5% citric acid | < 0.001 | 0.005 (Transitional SRL = 0.02)** |
| **Chromium *** | 7440-47-3 | 0.5% citric acid | 0.14 | 0.250 (Transitional SRL = 1.0)** |
| **Cobalt *** | 7440-48-4 | 0.5% citric acid | < 0.01 | 0.02 (Transitional SRL = 0.1)** |
| **Copper *** | 7440-50-8 | 0.5% citric acid | < 0.1 | 4 |
| **Iron *** | 7439-89-6 | 0.5% citric acid | 0.71 | 40 |
| **Lead *** | 7439-92-1 | 0.5% citric acid | 0.0037 | 0.010 (Transitional SRL = 0.04)** |
| **Lithium *** | 7439-93-2 | 0.5% citric acid | < 0.01 | 0.048 |
| **Magnesium *** | 7439-95-4 | 0.5% citric acid | < 0.01 | - |
| **Manganese *** | 7439-96-5 | 0.5% citric acid | 0.21 | 1.8 |

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| | | | | |
|---|---|---|---|---|
| **Mercury *** | 7439-97-6 | 0.5% citric acid | < 0.0002 | 0.003 (Transitional SRL = 0.015)** |
| **Molybdenum *** | 7439-98-7 | 0.5% citric acid | < 0.01 | 0.12 (Transitional SRL = 0.6)** |
| **Nickel *** | 7440-02-0 | 0.5% citric acid | 0.033 | 0.14 (Transitional SRL = 0.7)** |
| **Silver *** | 7440-22-4 | 0.5% citric acid | < 0.01 | 0.08 |
| **Thallium *** | 7440-28-0 | 0.5% citric acid | < 0.0001 | 0.0001 (Transitional SRL = 0.0005)** |
| **Tin *** | 7440-31-5 | 0.5% citric acid | < 0.01 | 100 |
| **Titanium *** | 7440-32-6 | 0.5% citric acid | < 0.1 | - |
| **Vanadium *** | 7440-62-2 | 0.5% citric acid | < 0.001 | 0.01 (Transitional SRL = 0.05)** |
| **Zinc *** | 7440-66-6 | 0.5% citric acid | < 0.1 | 5 |

* Limit values from the EU practical guideline on metals and alloys used in food contact materials and articles (CM/Res(2013)9
** Transitional limit values were communicated in a letter from "Department of Biological Standardisation, OMCL Network & HealthCare (DBO) Consumer Health Protection" to the national authorities on November 18, 2013. These limit values will be reconsidered after 3 years. To date the transitional SRL has not been reconsidered by the authorities yet.

**Summary and Evaluation of the Results**

For metals for repeated use, the sum of the results of the 1st and 2nd tests should not exceed an exposure equivalent to daily use for one week (i.e. seven times the SRL) and the specific release from the 3rd test should not exceed the specific release limit in the EU practical guide on metals and alloys used in food contact materials and articles (CM/Res(2013)9).

The repeated tests show that the product tested fulfils these requirements and the sample therefore **complies** with CM/Res(2013)9 for the above mentioned test conditions.

***Raw materials:***

The monomers and additives used in this product are all on *"the list of authorized monomers and other materials which may be used in the manufacture of plastics and articles"* and the *"incomplete list of additives which may be used in the manufacture of plastics materials and articles"*

*Dual Use Additives as defined in (EC) No 10/2011 are not used in the manufacture of these products*

***Testing is carried out by:***

Eurofins Product Testing A/S, Galten, Denmark

*All test reports are available on request.*

On behalf of MODU Valves A/S

Dato / date: 1/10-2023

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