



## DECLARATION OF CONFORMITY

For the following product

**DC006**

**2024-12**

### Type 3347

### Hygienic Angle Valve

<b>European regulation</b>
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Food contact
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The Hygienic Angle Valve Type 3347 meets the requirements of the food and pharmaceutical industry.

Manufacturing processes of Samson Regulation and those of its suppliers comply with the good manufacturing practices established by regulation (EC) No. 2023/2006<sup>1</sup>.

The valve components in contact with foodstuffs meet the following requirements:

- the metal parts are made of forged stainless steel 1.4404/316L (valve body and plug) or cast stainless steel 1.4409/A351 CF3M (valve body) in accordance with:
  - o the regulations (EC) No. 1935/2004<sup>2</sup>
  - o the Council of Europe Resolution CM/Res(2013)9 on metals and alloys used in food contact materials and articles;
  - o the French decree of 13 January 1976 on stainless steel materials and objects in contact with foodstuffs;
  - o the sheet published by the French authority DGCCRF: MCDA n°1 (V2 - 2017), Aptitude for food contact of metals and metal alloys intended to come into contact with foodstuffs.
- PTFE-guided version : The stem seal, which ensures the seal with the outside, is made of PTFE in accordance with:
  - o the regulations (EC) No. 1935/2004<sup>2</sup> and (EU) No. 10/2011<sup>3</sup> as amended  
The conditions and results of the overall and specific migration tests are detailed on Annex 1.
  - o with the recommendations LI & LII for PTFE, XXI for EPDM published by BfR (Federal Institute for Risk Assessment).
- PEEK-guided version:
  - o The steam seal, which ensures the seal with the outside, is made of PEEK in accordance with:
    - the Regulations (EC) No. 1935/2004<sup>2</sup> and (EU) No. 10/2011<sup>3</sup> as amended  
The conditions and results of our supplier's global and specific migration tests are available on Annex 2.
  - o The body seal is made of PTFE in accordance with:

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<sup>1</sup> Regulation (EC) No 2023/2006 on good manufacturing practice for materials and articles intended to come into contact with food

<sup>2</sup> Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food

<sup>3</sup> Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, as last amended by Regulation (EU) No 2020/1245



- the regulations (EC) No. 1935/2004<sup>2</sup> and (EU) No. 10/2011<sup>3</sup> as amended  
The conditions and results of the overall and specific migration tests are detailed on Annex 1.
- with the recommendations LI & LII for PTFE, XXI for EPDM published by BfR (Federal Institute for Risk Assessment).
- Anti-crystallizing version :
  - The compensating ring, which participates in the tightness with the metal centering ring, is made of EPDM in accordance with :
    - the regulation (EC) No. 1935/2004<sup>2</sup>
    - the French Order of 5 August 2020 on rubber materials and articles intended to come into contact with foodstuffs and soothers for infants and young children;
    - the sheet published by the French authority DGCCRF: MCDA n°3 (V3 - 2021), Aptitude for food contact of organic plastic materials intended to come into contact with foodstuffs;

The conditions and results of our supplier's global and specific migration tests are available on Annex 1.
  - The body seal is made of PTFE in accordance with:
    - the regulations (EC) No. 1935/2004<sup>2</sup> and (EU) No. 10/2011<sup>3</sup> as amended  
The conditions and results of the overall and specific migration tests are detailed on Annex 1.
    - with the recommendations LI & LII for PTFE, XXI for EPDM published by BfR (Federal Institute for Risk Assessment).
  - The HT-S1 surface treatment of the steam in accordance with:
    - the regulations (EC) No. 1935/2004<sup>2</sup>
    - the Council of Europe Resolution CM/Res(2013)9 on metals and alloys used in food contact materials and articles;
    - the French decree of 13 January 1976 on stainless steel materials and objects in contact with foodstuffs;
    - the sheet published by the French authority DGCCRF: MCDA n°1 (V2 - 2017), Aptitude for food contact of metals and metal alloys intended to come into contact with foodstuffs.
- The optional valve seals, which provide the internal seal, are made of PEEK Natural Food & Life Science Grade and according to our supplier's declaration of conformity comply with:
  - the Regulations (EC) No. 1935/2004<sup>2</sup> and (EU) No. 10/2011<sup>3</sup> as amended  
The conditions and results of our supplier's global and specific migration tests are available on Annex 2.

According to the migration tests carried out on the plastic components in accordance with Regulation (EU) No 10/2011<sup>3</sup> as amended, the overall and specific migrations remain within the limits set by the above-mentioned Regulation when the complete apparatus is used under the conditions indicated below:

- repeated short-term and long-term contact with all kinds of foodstuffs in applications at room temperature up to 121 °C.

#### Environmental regulation and others

The Hygienic Angle Valve Type 3347 is compliant with

- Directive RoHS 2011/65/EU, 2015/863/EU
- Regulation REACH 1907/2006/EC

#### USA regulation

##### Food contact and pharmaceutical regulations

The Type 3347 Hygienic Angle Valve meets the requirements of the food industries according to the following parameters.

- The PTFE used in the manufacture of the seals, in direct contact with the fluid complies with :
  - o FDA regulation 21 CFR §177.1550,
  - o USP Class VI 121°C
- The PEEK used in the manufacture of the seals complies with :
  - o FDA regulation 21 CFR §177.2415,
  - o USP Class VI 121°C
- The composition of EPDM used in the manufacture of the seals, complies with :
  - o the regulation FDA CFR 21 §177.2600,
  - o USP Class VI 121°C
- The grease used for the assembly of parts in contact with the fluid, complies with :
  - o the regulation FDA CFR 21 §178.3570,
  - o NSF-H1 requirements
- The HT-S1 surface treatment of the steam complies with :
  - o FDA

#### Chinese regulation

##### Food contact

The Hygienic Angle Valve Type 3347 meets the requirements of the Chinese food and pharmaceutical industries.

The valve components that come into contact with foodstuffs meet the following requirements:

- the metal parts are made of forged stainless steel 1.4404/316L (valve body and plug) or cast stainless steel 1.4409/A351 CF3M (valve body) in accordance with:
  - o the regulations GB 4806.1-2016<sup>4</sup> and GB 4806.9-2023<sup>4</sup>
  - o The conditions and results of the overall and specific migration tests are detailed on Annex 3.

<sup>4</sup> Regulation GB 4806.1-2016 on general safety requirements for materials and articles intended to come into contact with food; GB 4806.7-2023 for plastic materials, GB 4806.9-2023 for metal



- PTFE-guided version : The stem seal, which seals to the outside, is made of PTFE:
  - Our supplier's declaration of conformity certifies that this material complies with regulations GB 4806.1-2016<sup>4</sup>, GB 4806.7-2023<sup>4</sup> and GB 9685-2016<sup>5</sup>;
  - The conditions and results of the overall and specific migration tests are detailed on Annex 3.
- PEEK-guided version:
  - The steam seal, which ensures the seal with the outside, is made of PEEK :
    - Our supplier's declaration of conformity certifies that this material complies with regulations GB 4806.1-2016<sup>4</sup>, GB 4806.7-2023<sup>4</sup> and GB 9685-2016<sup>5</sup>
    - The conditions and results of our supplier's global and specific migration tests are available on Annex 2.
  - The body seal is made of PTFE :
    - Our supplier's declaration of conformity certifies that this material complies with regulations GB 4806.1-2016<sup>4</sup>, GB 4806.6-2016<sup>4</sup> and GB 9685-2016<sup>5</sup>;
    - The conditions and results of the overall and specific migration tests are detailed on Annex 3
- Anti-crystallizing version :
  - The compensating ring, which participates in the tightness with the metal centering ring, is made of EPDM in accordance with :
    - the regulations GB 4806.1-2016<sup>4</sup> and GB 4806.9-2023<sup>4</sup>
    - The conditions and results of the overall and specific migration tests are detailed on Annex 3
  - The body seal is made of PTFE :
    - Our supplier's declaration of conformity certifies that this material complies with regulations GB 4806.1-2016<sup>4</sup>, GB 4806.7-2023<sup>4</sup> and GB 9685-2016<sup>5</sup>;
    - The conditions and results of the overall and specific migration tests are detailed on Annex 3
- the optional plug seals, which provide the internal seal, are made of PEEK natural Food & Life Science Grade:
  - Our supplier's declaration of conformity certifies that this material complies with regulations GB 4806.1-2016<sup>4</sup>, GB 4806.7-2023<sup>4</sup> and GB 9685-2016<sup>5</sup>;
  - The conditions and results of our supplier's global and specific migration tests are available on Annex 2.

#### Environmental regulation and others

The Hygienic Angle Valve Type 3347 meets the requirements of :

- China RoHS 2.0 GB/T26572-2011

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<sup>5</sup> Regulation GB 9685-2016 on the use of additives in materials intended to come into contact with food



**Other regulations**

The composition of the plastical materials in contact with the fluid is :

- Free of animal-derived ingredients (ADI free) and thus free of TSE/BFE
- Free of human-derived ingredients
- Purely of synthetic origin.

SAMSON REGULATION S.A.S.

A handwritten signature in black ink, consisting of a stylized 'B' followed by a horizontal line and a small flourish.

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Bruno Soulas  
General Director  
Head of Strategy and Development

SAMSON REGULATION S.A.S.

A handwritten signature in black ink, consisting of a stylized 'S' followed by a horizontal line and a small flourish.

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Sabrina Durand  
Quality certification engineer

## Annex 1 – European food contact regulation

### Detailed conditions and results of migration tests on the PTFE seals

According to the migration tests carried out on the plastic components in accordance with Regulation (EU) No 10/2011<sup>3</sup> as amended, the overall and specific migrations remain within the limits set by the above-mentioned Regulation when the complete apparatus is used under the conditions indicated below:

- for all foodstuffs specified due to the satisfactory results obtained with simulants A, B and D2 (Annex III Tables 1 and 3);
- under the conditions covered by the tests: applications at a maximum temperature of 121°C (according to Annex V Chapter 3 Table 3).

### **Overall migration (OM)**

The maximum limit on the overall migration (OML) has been tested and measured in accordance with the following table:

Test conditions	Simulant	Duration	Temperature	Ratio surface / volume (dm <sup>2</sup> /dl)	OML (mg/dm <sup>2</sup> )	Result (mg/dm <sup>2</sup> )
MG 5	A : 10% ethanol	2 h	100°C	1	10	1.3
MG 5	B : 3% acetic acid	2 h	100°C	1	10	1.5
MG 5	D2 : Oil	2 h	100°C	1	10	1.0

### **Specific migration (SM)**

The maximum limits on the specific migration (SML) of substances authorised in the annexes I and II of the Regulation (EU) No. 10/2011<sup>3</sup> as amended have been tested and measured in accordance with the following tables:

Monomer	FCM No	CAS No	SML (mg/kg)	Status
TFE = tetrafluorethylene	281	116-14-3	0.05	OK
PPVE = Perfluoropropylvinyl Ether	423	1623-05-8	0.05	OK
hexafluoropropylene	282	116-15-4	0.01	OK

Metal	SML (mg/kg)	Result (mg/kg)	Status	Metal	SML (mg/kg)	Result (mg/kg)	Status
Al	1	<0.1	OK	Hg	0.01	<0.01	OK
As	0.01	<0.01	OK	La	0.05	<0.05	Ok
Ba	1	<0.5	OK	Li	0.6	<0.2	OK
Cd	0.002	<0.002	OK	Mn	0.6	<0.2	Ok
Co	0.05	<0.02	OK	Ni	0.02	<0.02	OK
Cr	0.01	<0.01	OK	Pb	0.01	<0.01	OK
Cu	5	<2	OK	Sb	0.04	<0.04	OK
Eu	0.05	<0.05	OK	Tb	0.05	<0.05	OK
Fe	48	<10	OK	Zn	5	<1	OK
Ga	0.05	<0.05	OK				

### Detailed conditions and results of migration tests on the EPDM seals

According to the migration tests carried out on the plastic components in accordance with the French Order of 5 August 2020 on rubber materials and articles intended to come into contact with foodstuffs and soothers for infants and young children, the overall and specific migrations remain within the limits set by the above-mentioned Regulation when the complete apparatus is used under the conditions indicated below:

- for all foodstuffs specified due to the satisfactory results obtained with simulants A, B and D2 (Annex III Tables 1 and 3 of the regulation (EU) No 10/2011<sup>3</sup>);
- under the conditions covered by the tests: applications at a maximum temperature of 121°C (according to Annex V Chapter 3 Table 3 of the regulation (EU) No 10/2011<sup>3</sup>).

#### Overall migration (OM)

The maximum limit on the overall migration (OML) has been tested and measured in accordance with the following table:

Test conditions	Simulant	Duration	Temperature	Ratio surface / volume (dm <sup>2</sup> /dl)	OML (mg/dm <sup>2</sup> )	Result (mg/dm <sup>2</sup> )
MG 5	A : 10% ethanol	2 h	Back flow temperature	1	10	<1
MG 5	B : 3% acetic acid	2 h	Back flow temperature	1	10	<1
MG 5	D2 : 95% ethanol	4 h	60°C	1	10	4.0
MG 5	Isooctane	2 h	60°C	1	10	9.6

#### Specific migration (SM)

The maximum limits on the specific migration (SML) of substances authorised in the article 6 of the French order of 5 August 2020 have been tested and measured in accordance with the following tables:

Monomer	FCM No	CAS No	SML (mg/kg)	Status
hexafluoropropylene	282	116-15-4	0.01	OK

Metal	SML (mg/kg)	Result (mg/kg)	Status
Al	1	<0.1	OK
Ba	1	<0.5	OK
Cu	5	<2	OK
Zn	10	<10	OK

## Annex 2 / Annexe 2



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### BIOCOMPATIBILITY TEST RESULTS

A biocompatibility type testing programme was run by an independent, internationally renowned and accredited testing organisation on **Ketron® LSG PEEK Food Grade natural** stock shapes (1) in order to check their compliance with both United States Pharmacopeia (USP) and ISO 10993-1 guideline requirements for Biocompatibility Testing of Materials. The test results reproduced in the table below indicate that, under the experimental conditions utilised in the testing, the examined Mitsubishi Chemical Advanced Materials Life Science Grade meets the requirements of the USP and ISO guidelines that are referenced (2).

TESTS (2)	MATERIAL ⇒	Ketron LSG PEEK Food Grade natural
<b>1. Systemic Toxicity (acute)</b> Ref.: ISO 10993-11 and USP <88> Biological Reactivity Tests, In Vivo - Systemic Injection Test (121°C/1 h ; 72 h exposure) 0.9% NaCl USP solution extract		non-toxic
1:20 solution of ethanol in 0.9% NaCl USP solution extract		non-toxic
cottonseed oil extract		non-toxic
polyethylene glycol 400 extract		non-toxic
<b>2. Intracutaneous Reactivity</b> Ref.: ISO 10993-10 and USP <88> Biological Reactivity Tests, In Vivo - Intracutaneous Test (121°C/1 h ; 72 h exposure) 0.9% NaCl USP solution extract		negligible
1:20 solution of ethanol in 0.9% NaCl USP solution extract		negligible
cottonseed oil extract		negligible
polyethylene glycol 400 extract		negligible
<b>3. Implantation Test</b> Ref.: USP <88> Biological Reactivity Tests, In Vivo - Implantation Test (7 days)		no reaction
<b>USP Class VI conformity (conclusion from tests 1, 2 and 3)</b>		yes
<b>4. Sensitization</b> Ref. ISO 10993-10 Magnusson & Kligman Maximization Method (121°C/1 h ; 0.9% NaCl USP solution extract and cottonseed oil extract)		no evidence of sensitization
<b>5. Cytotoxicity</b> Ref.: ISO 10993-5 and USP <87> Biological Reactivity Tests, In Vitro Elution test (L929 cell culture ; MEM-Complete extract, 37°C/24 h ; incubation period: 48 h at 37°C)		non-cytotoxic
<b>6. Human blood compatibility</b> Ref.: ISO 10993-4 Indirect Hemolysis (in-vitro) - (121°C/1 h ; 0.9% NaCl USP solution extract)		non-hemolytic
<b>7. USP-Physicochemical Tests for Plastics</b> Ref.: USP <661> Containers (Ultra Pure Water extract, 70°C/24h)		
non-volatile residue (USP-limit: 15 mg)		0.2 mg
residue on ignition (3) (USP-limit: 5 mg)		NR
heavy metals (USP-limit: 1 ppm)		< 1 ppm
buffering capacity (USP-limit: 10 ml)		< 0.1 ml
<b>8. Heavy metal content (mg/kg) - (4)</b>		
Cadmium		< 0.5
Chromium		< 5
Lead		< 1
Mercury		< 0.5

NR: no result to report

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- (1) : All tests were run on test specimens machined from rod diameter 50 mm shortly after manufacture (production order numbers 64732 & 8254038). All LSG stock shapes are made from the same resin grade as the one that has been used for the manufacture of the stock shapes that were the subject of the biocompatibility type testing programme.
- (2) : Mitsubishi Chemical Advanced Materials performs testing on its Life Science Grades in order to facilitate evaluation by its customers of their biocompatibility with regard to the requirements applicable to the specific use of the finished product. However, Mitsubishi Chemical Advanced Materials does not possess expertise in evaluating the suitability of its tested materials for use in specific medical, pharmaceutical, or biotechnological applications. **It remains the customer's sole responsibility to test and assess the suitability of Mitsubishi Chemical Advanced Materials' Life Science Grades for its intended applications, processes and uses.**

Mitsubishi Chemical Advanced Materials makes no warranties or representations whatsoever that its materials are manufactured in accordance with the quality standards appropriate and necessary for materials intended for use in implantable medical device applications and in applications that are essential to the restoration or continuation of a bodily function important to the continuation of human life.

**Mitsubishi Chemical Advanced Materials' Life Science Grades should not be used for applications involving medical devices that are intended to remain implanted in the human body continuously for a period exceeding 24 hours (30 days\*), or are intended to remain in contact with internal human tissue or bodily fluids for more than 24 hours (30 days\*). They should not be used either for the manufacture of critical components of medical devices that are essential to the continuation of human life.**

\*: '30 days' applies to Ketron PEEK-CLASSIX™ LSG white only.

By accepting delivery of the Mitsubishi Chemical Advanced Materials Life Science Grade product, the customer acknowledges the foregoing conditions.

- (3) : This part of the test is not to be performed when the non-volatile residue test result does not exceed 5 mg.
- (4) : Detection limits of the ICP-MS testing device used: Cadmium: 0.5 ; Chromium: 5; Lead: 1 ; Mercury: 0.5 mg/kg

#### NOTES:

- Finished life science grade articles shall be manufactured such that the surface skin(s) of the semi-finished products is (are) taken away.
- It is the responsibility of the buyer to assure the traceability of the material during any further downstream use up to and including the finish machined part as well as the equipment in which it is assembled.

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\*: '30 days' applies to Ketron® PEEK-CLASSIX™ LSG white only.

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**DÉCLARATION DE CONFORMITÉ DE MATÉRIAUX DESTINÉS À ENTRER EN  
CONTACT AVEC DES DENRÉES ALIMENTAIRES <sup>(1)</sup>**

Déclaration établie le: 1 septembre 2022 <sup>(2)</sup>

**Mitsubishi Chemical Advanced Materials N.V.**  
**Industriepark Noord**  
**Galgenveldstraat 12**  
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Le déclarant et fabricant des produits concernés confirme par la présente déclaration que les produits:

**“Ketron® LSG PEEK Food Grade naturel” [PEEK]**

**Produits demi-finis: barres rondes, plaques et tubes <sup>(3)</sup> et**

**Articles finis fabriqués à partir de ces produits demi-finis par Mitsubishi Chemical Advanced Materials**

**Union européenne**

Les produits mentionnés ci-dessus

- sont conformes aux exigences des articles 3, 11(5), 15 et 17 du Règlement (CE) N° 1935/2004,
- sont conformes aux exigences applicables du Règlement (UE) N° 10/2011 modifié, intégrant le Règlement de la Commission (UE) N° 2020/1245,
- sont conformes aux exigences de GB 4806.1 - 2016,
- sont conformes aux exigences applicables du GB 9685 - 2016 et GB 4806.7 - 2016 et leurs annonces pertinentes,
- sont fabriqués conformément aux bonnes pratiques de fabrication (BPF) établies par le Règlement (CE) N° 2023/2006 du 22 décembre 2006 relatif aux bonnes pratiques de fabrication des matériaux et objets destinés à entrer en contact avec des denrées alimentaires.
- sont fabriqués conformément aux bonnes pratiques de fabrication (BPF) établies par GB 31603-2015.

Selon les tests de migration réalisés sur les produits conformément au Règlement (UE) N° 10/2011 modifiés, GB 4806.7 - 2016, GB 5009.156 - 2016 et GB 31604.1 - 2015, l'indice sensoriel, la migration globale, la consommation de permanganate de potassium, la fraction de métaux lourds ainsi que la migration spécifique reste dans les limites globales fixées par le Règlement (UE) 10/2011 et GB 4806.7 - 2016 lorsqu'ils sont utilisés dans les conditions indiquées ci-dessous.

**Spécifications relatives à l'utilisation prévue des produits :**

- Type(s) de denrées alimentaires destinées à entrer en contact répété avec le matériau:  
**Tous types de denrées**
- Type(s) de denrées alimentaires NON destinées à entrer en contact répété avec le matériau:  
**Sans objet**
- Durée et température de traitement et stockage en contact avec l'aliment:

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- **Test de migration globale effectué sous les conditions d'essai normalisées**  
*l'éthanol à 10 % (4 h à la température de reflux),  
l'éthanol à 50 % (4 h à la température de reflux),  
l'acide acétique à 3 % (4 h à la température de reflux),  
l'acide acétique à 4 % (4 h à la température de reflux) et  
l'huile végétale (2h à 175 °C)*
- **Test de migration spécifique à**  
*L'acide acétique à 3 % (4 h à la température de reflux),  
L'acide acétique à 4 % (4 h à la température de reflux),  
L'éthanol à 10 % (4 h à la température de reflux),  
L'éthanol à 50 % (4 h à la température de reflux) et  
L'huile végétale (2h à 175 °C) <sup>1</sup>*
- Rapport (S/V) entre la surface du produit et le volume de denrée alimentaire à son contact utilisé pour établir la conformité des produits :  
 **$S/V = 6 \text{ dm}^2/\text{kg}$**

Les résultats du test de migration globale sont exprimés dans le tableau ci-dessous:

<b>L'éthanol à 10 %</b>	<b>L'éthanol à 50 %</b>	<b>L'acide acétique à 3 %</b>	<b>L'acide acétique à 4 %</b>	<b>L'huile végétale</b>
0.8 mg/dm <sup>2</sup>	0.5 mg/dm <sup>2</sup>	0.8 mg/dm <sup>2</sup>	0.7 mg/dm <sup>2</sup>	< 1.0 mg/dm <sup>2</sup>

Les substances suivantes, soumises à des restrictions selon le Règlement (UE) 10/2011 et GB 4806.6-2016 modifié, sont utilisées dans les produits :

<b>Dénomination chimique des substances</b>	<b>Restrictions</b>
4,4'-Difluorobenzophénone (N° CAS 345-92-6)	LMS = 0,05 mg/kg
1,4-Dihydroxybenzène (N° CAS 123-31-9)	LMS = 0,6 mg/kg
Substances brevetées <sup>(4)</sup>	

Les substances suivantes, identifiées comme additif ou arôme à double usage selon le Règlement (UE) 10/2011 modifié, sont utilisées dans les produits:

<b>Dénomination chimique des substances</b>
Substances brevetées <sup>(4)</sup>

Une évaluation des risques des substances non inscrites (NLS), telles que les catalyseurs et les substances non intentionnellement ajoutées (NIAS), telles que les produits de réaction et de dégradation, a été réalisée conformément à l'article 3 du règlement-cadre ((UE) 1935/2004) et à l'article 19 du règlement sur les matières plastiques ((UE) 10/2011) et à l'article 3.5 de GB 4806.1 - 2016, sur base des conditions susmentionnées.

<sup>1</sup> Le test de migration spécifique à l'huile végétale (2h à 175 °C) étant remplacé par des tests à l'isooctane (4 h, 60 °C), à l'éthanol 95 % (6 h, 60 °C) et à l'MPPO (2h à 175 °C) conformément à la Directive 82/711/CEE parce que le test de migration à l'huile végétale n'est pas réalisable pour des raisons techniques liées à la méthode d'analyse.



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### États-Unis

Dans le cadre des législations en vigueur aux États-Unis d'Amérique (FDA) concernant les matériaux et objets en matière plastique destinés à entrer en contact avec les denrées alimentaires, nous vous donnons les informations suivantes des demi-produits de Mitsubishi Chemical Advanced Materials mentionnés ci-dessus :

- **Ketron LSG PEEK Food Grade naturel** est conforme aux exigences de la réglementation FDA 21 CFR § 177.2415 "Résines poly(aryléthercétone)" [FDA regulations 21 CFR § 177.2415 "Poly(aryletherketone) resins"].

Les demi-produits **Ketron LSG PEEK Food Grade naturel** sont essentiellement adaptés à la fabrication d'objets destinés à l'utilisation répétée en contact avec les denrées alimentaires de toutes sortes types I to IX, à l'exclusion des préparations pour nourrissons et du lait maternel, suivant les conditions d'utilisation A à H, comme décrites dans le tableaux 1 et 2 en 21 CFR 176.170(c), respectivement.

### Japon

Dans le cadre des législations tel qu'établi par le ministère japonais de la Santé, du Travail et du Bien-être (MHLW) dans l'Avis officiel (Avis n° 196 de 2020) du 28 avril 2020 pour les ustensiles, récipients et emballages destinés à entrer en contact avec des denrées alimentaires, nous vous donnons les informations suivantes basées sur l'état de conformité en ce qui concerne leur composition, des matières premières utilisées à ce jour par Mitsubishi Chemical Advanced Materials pour la fabrication des demi-produits mentionnés ci-dessus :

- la composition du **Ketron LSG PEEK Food Grade naturel** est conforme aux exigences de composition des listes positives japonaises de contact alimentaire "Polymères de base (plastiques)" et "Additifs".  
Basé sur leur composition, les demi-produits en **Ketron LSG PEEK Food Grade naturel** sont essentiellement adaptés à la fabrication d'objets destinés à l'utilisation en contact avec les denrées alimentaires de toutes sortes types, dans des conditions de température maximale III.

Il appartient toutefois au client faisant l'usage auquel il est destiné de l'objet en plastique fabriqué à partir de ces produits, de vérifier l'adéquation finale du matériau plastique à l'application prévue au contact de denrées alimentaires; il doit par exemple vérifier que les propriétés physiques du matériau plastique le rendent approprié à l'usage auquel il est destiné, vérifier la conformité des objets finis en plastique en termes de limites de migration, vérifier l'incidence éventuelle du matériau plastique sur la composition et/ou les propriétés organoleptiques de l'aliment, etc...

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- (1) Règlement (CE) N° 1935/2004 du Parlement Européen et du Conseil du 27 octobre 2004 relatif aux matériaux et objets destinés à entrer en contact avec des denrées alimentaires, remplaçant les Directives 80/590/CEE et 89/109/CEE – Article 16.
- (2) La durée de validité de la présente déclaration est de 5 ans à compter de sa date de délivrance, sauf en cas de modification de la réglementation ou de la composition nécessitant une réévaluation avant expiration.
- (3) Pour toutes informations concernant les dimensions disponibles, nous vous invitons à contacter votre bureau de vente Mitsubishi Chemical Advanced Materials.
- (4) Des substances soumises à des restrictions selon le Règlement (UE) 10/2011 modifié, sont utilisées dans les produits. L'identité de ces substances pourra être communiquée à des tiers qui en feront la demande (par ex. des laboratoires d'essai) aux termes d'un Accord de non-divulgateion.

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**NOTES :**

- Les articles finis destinés au contact alimentaire seront fabriqués de manière à retirer la/les pellicules de surface des produits demi-finis.
- Il appartient toutefois au client faisant l'usage auquel il est destiné de l'objet en plastique fabriqué à partir de ces produits, que conformément aux bonnes pratiques de fabrication, les articles finis destinés au contact alimentaire, seront soigneusement nettoyés avant leur première utilisation en contact avec des denrées alimentaires.
- La présente déclaration de conformité est exclusivement valide pour des produits portant le « label approprié pour contact alimentaire » (autocollant) de Mitsubishi Chemical Advanced Materials, le « label raison sociale » approprié (autocollant) de Mitsubishi Chemical Advanced Materials, et le label (autocollant) comportant le « numéro d'ordre de production » unique permettant la traçabilité. Pour les articles finis, ces autocollants se trouvent sur le produit même ou sur son emballage.
- Il incombe à l'acheteur de vérifier la traçabilité du matériau pour toute autre utilisation en aval jusqu'à et y compris la pièce usinée finie ainsi que les équipements dans lesquels elle est assemblée.

**Ketron® est une marque déposée du Mitsubishi Chemical Advanced Materials Group.**

Les déclarations, les informations techniques, les recommandations et les conseils sont communiqués à titre informatif uniquement. Ils ne sont pas destinés à constituer une garantie de quelque type que ce soit ni une condition de vente, et ne doivent pas être interprétés comme tels. Il est toutefois porté à l'attention du lecteur que Mitsubishi Chemical Advanced Materials ne garantit pas l'exactitude ni l'exhaustivité de ces informations, et qu'il incombe au client de tester et d'évaluer l'adéquation des produits de Mitsubishi Chemical Advanced Materials pour toute application donnée ou pour leur utilisation dans un dispositif fini.

Les produits de Mitsubishi Chemical Advanced Materials ne doivent pas être utilisés dans des applications impliquant des dispositifs médicaux destinés à rester implantés dans le corps humain de manière continue pendant plus de 24 heures (30 jours\*), ou destinés à rester en contact avec les tissus humains internes ou les fluides corporels pendant plus de 24 heures (30 jours\*), ou comme composants essentiels de dispositifs médicaux vitaux.

\* : la période de « 30 jours » s'applique uniquement au produit Ketron® PEEK-CLASSIX™ LSG blanc.

Mitsubishi Chemical Advanced Materials n'est pas un fabricant de dispositifs médicaux et les informations contenues dans le présent document ne constituent en aucun cas une garantie ou une représentation expresse ou implicite de quelque nature que ce soit, y compris, mais sans s'y limiter, toute garantie prévue par les lois applicables, toute garantie implicite de qualité marchande ou d'adéquation à un usage particulier, toute garantie contre les vices cachés ou les défauts ou vices rédhibitoires, ni une garantie que les produits de Mitsubishi Chemical Advanced Materials sont fabriqués conformément aux normes de qualité appropriées et nécessaires pour les matériaux destinés à être utilisés dans des applications de dispositifs médicaux implantables et dans des applications essentielles à la restauration ou à la poursuite d'une fonction corporelle vitale.

PEEK-CLASSIX™ est une marque d'Invivo Ltd.



### Annex 3 – Chinese food contact regulation

According to the migration tests carried out on plastic and metal parts in accordance with the regulations GB 31604-2015<sup>6</sup> and GB 5009.156-2016<sup>7</sup>, the overall and specific migration remains within the limits set by the above-mentioned regulations when the complete apparatus is used under the conditions indicated below:

- for all foodstuffs (acc. to annex A Table A1) due to the satisfactory results obtained with the simulants (Tables 1 and 2);

- under the conditions covered by the tests: high-temperature applications at a maximum temperature of 121 °C (according to table 6).

#### Detailed conditions and results of migration test on metallic parts in stainless steel 1.4404 / 316 L

##### Overall migration (OM)

The maximum limit on the overall migration (OML) has been tested and measured in accordance with the following table:

Simulant	Duration	Temperature	Ratio Surface / volume (dm <sup>2</sup> /dl)	OML (mg/dm <sup>2</sup> )	Results (mg/dm <sup>2</sup> )
10% ethanol	2h	Back flow temperature	1	10	0.8
4% acetic acid	2h	Back flow temperature	1	10	0.7
95% ethanol	3.5h	*60°	1	10	1.3
Isooctane	1.5h	*60°	1	10	1.2

\*The OL 95% and ISO test conditions correspond to conventional fatty medium substitution test conditions (2 h at 100°C). These conditions are quoted in the European standard ISO 1186-1 (2002)

##### Specific migration (SM)

The maximum limit on the specific migration (SML) of substances authorized by the Regulation GB 4806.9<sup>4</sup> has been tested and measured in accordance with the following table:

Simulant	Duration	Temperature	Item	Results (mg/kg)	SML (mg/kg)	Status
4% acetic acid	2h	Back flow temperature	As	<0.01	< 0.04	OK
			Cd	<0.002	< 0.02	OK
			Cr	0.11	< 2.0	OK
			Ni	0.10	< 0.5	OK
			Pb	<0.01	< 0.05	OK

#### Detailed conditions and results of migration test on metallic parts in stainless steel 1.4409 / A351 CF3M

##### Overall migration (OM)

The maximum limit on the overall migration (OML) has been tested and measured in accordance with the following table:

Simulant	Duration	Temperature	Ratio Surface / volume (dm <sup>2</sup> /dl)	OML (mg/dm <sup>2</sup> )	Results (mg/dm <sup>2</sup> )
10% ethanol	2h	Back flow temperature	1	10	0.8
4% acetic acid	2h	Back flow temperature	1	10	0.7
95% ethanol	3.5h	*60°	1	10	1.3
Isooctane	1.5h	*60°	1	10	1.2

\*The OL 95% and ISO test conditions correspond to conventional fatty medium substitution test conditions (2 h at 100°C). These conditions are quoted in the European standard ISO 1186-1 (2002)

<sup>6</sup> Regulation GB 31604-2015 on the general principles for migration testing.

<sup>7</sup> Regulation GB 5009.156-2016 on the method of pre-treatment of materials and articles intended to come into contact with foodstuffs



### Specific migration (SM)

The maximum limit on the specific migration (SML) of substances authorized by the Regulation GB 4806.9<sup>4</sup> has been tested and measured in accordance with the following table:

Simulant	Duration	Temperature	Item	Results (mg/kg)	SML (mg/kg)	Status
4% acetic acid	2h	Back flow temperature	As	<0.01	< 0.04	OK
			Cd	<0.002	< 0.02	OK
			Cr	0.069	< 2.0	OK
			Ni	0.10	< 0.5	OK
			Pb	<0.01	< 0.05	OK

### Detailed conditions and results of migration test on PTFE seals

#### Overall migration (OM)

The maximum limit on the overall migration (OML) has been tested and measured in accordance with the following table:

Simulant	Duration	Temperature	Ratio surface / volume (dm <sup>2</sup> /dl)	OML (mg/dm <sup>2</sup> )	Results (mg/dm <sup>2</sup> )
10% ethanol	2 h	Back flow temperature	1	10	1.3
4% acetic acid	2 h	Back flow temperature	1	10	1.5
Vegetal oil	2 h	Back flow temperature	1	10	1.9

### Specific migration (SM)

The maximum limits on the specific migration (SML) of substances authorized by the Regulation GB 4806.7<sup>4</sup> and GB 4806.9<sup>4</sup> have been tested and measured in accordance with the following tables:

Polymer name	No	CAS No	SML (mg/kg)	Status
PTFE= Polytetrafluoro- Ethylène	87	9002-84-0	0.05	OK
FEP = hexafluoropropylène	85	25067-11-2	0.01	OK

Simulant	Duration	Temperature	Item	Results (mg/kg)	SML (mg/kg)	Status
4% acetic acid	2h	Back flow temperature	As	<0.01	< 0.04	OK
			Cd	<0.002	< 0.02	OK
			Cr	0.01	< 2.0	OK
			Ni	0.02	< 0.5	OK
			Pb	0.01	< 0.05	OK

### Detailed conditions and results of migration test on EPDM seals

#### Overall migration (OM)

The maximum limit on the overall migration (OML) has been tested and measured in accordance with the following table:

Simulant	Duration	Temperature	Ratio surface / volume (dm <sup>2</sup> /dl)	OML (mg/dm <sup>2</sup> )	Results (mg/dm <sup>2</sup> )
10% ethanol	2h	Back flow temperature	1	10	<1
4% acetic acid	2h	Back flow temperature	1	10	<1
95% Ethanol	3.5h	*60°	1	10	4.8
Isooctane	1.5h	*60°	1	10	8.8

\*The OL 95% and ISO test conditions correspond to conventional fatty medium substitution test conditions (2 h at 100°C). These conditions are quoted in the European standard ISO 1186-1 (2002)



### Specific migration (SM)

The maximum limits on the specific migration (SML) of substances authorized by the Regulation GB 4806.7<sup>4</sup> and GB 4806.9<sup>4</sup> have been tested and measured in accordance with the following tables:

Polymer name	No	CAS No	SML (mg/kg)	Status
FEP = hexafluoropropylène	85	25067-11-2	0.01	OK

Simulant	Duration	Temperature	Item	Results (mg/kg)	SML (mg/kg)	Status
4% acetic acid	2h	Back flow temperature	As	<0.01	< 0.04	OK
			Cd	<0.002	< 0.02	OK
			Cr	<0.01	< 2.0	OK
			Ni	<0.02	< 0.5	OK
			Pb	<0.01	< 0.05	OK