

DECLARATION OF COMPLIANCE

All information contained in this document relates to the complete range of our products:

**INSIDE CéRAM™, INSIDE DisRAM™, FILTANIUM™, ISOFLUX™, ETERNIUM™ MEMBRANES
GASKETS
HOUSINGS**

Available diameters :

- Ø10-1 ch / Ø10-7 chs
- Ø20-1 ch / Ø20-5 chs / Ø20-13 chs / Ø20-32 chs / Ø20-61 chs
- Ø25-7 chs / Ø25-8 chs / Ø25-11 chs / Ø25-19 chs / Ø25-23 chs / Ø25-49 chs / Ø25-93 chs
- Ø41-25 chs / Ø41-37 chs / Ø41-61 chs

The structure of TAMI ceramic membranes is asymmetrical with circular and non-circular channels. The active surface area is obtained by adding a porous layer upon the support. The pore diameter increases in size when taken from the top of the active layer

The ceramic support is made of Titania.

The active layer is in contact with the fluid and determines porosity (cut-off). The active layer is porous with predetermined diameters permitting the desired molecular sizes to pass through whilst retaining larger sizes. The range of cut-off is:

- | | |
|--|---|
| • Fine Ultrafiltration (Fine UF) : 8, 5, 3, 1 kg/mol | Titania (TiO ₂) |
| • Ultrafiltration (UF) : 500, 300, 150, 100, 50, 10, 15 kg/mol | Titania (TiO ₂) and/or Zirconia (ZrO ₂) |
| • Microfiltration (MFT) : 1.4, 0.8, 0.45, 0.3, 0.2, 0.14 µm | Titania (TiO ₂) and/or Zirconia (ZrO ₂) |

For easy recognition, the end sealings are colour coded:

- gray PTFE for Microfiltration and **ISOFLUX™** membranes
- green PTFE for Ultrafiltration and Fine Ultrafiltration

The **ISOFLUX™** membrane ensures a constant permeate flux throughout the membrane. The thickness of the active layer decreases from the inlet to the outlet in order that the ratio pressure / thickness of the layers stays constant.

The **ISOFLUX™** membrane has a direction of flow which is clearly indicated on each membrane, and must be respected.

An initial cleaning is recommended prior to use.

NYONS March 2, 2021

Gaëlle Balduchi
Quality Manager, TAMI INDUSTRIES



Food Contact Regulations

The complete range of TAMI ceramic membranes, housings and gaskets meet the requirements for materials intended to come into contact with food in that:

INSIDE CéRAM™, INSIDE DisRAM™, FILTANIUM™, ISOFLUX™, ETERNIUM™ MEMBRANES HOUSING

- **EU**

TAMI Ceramic Membranes and housings meet the requirements for food contact as details in European food Regulations (EC) Number 1935/2004 in that:

- ✓ the products are manufactured according to the directive for GMP (Good Manufacturing Practice) 2023/2006/EC based on the establishment of a Quality Assurance System for more than 20 years
- ✓ the ceramic materials of construction satisfy the European Commission Ceramics Directive 84/500/CEE (as amended by 2005/31/EC) following analytical certification of compliance in relation to lead and cadmium leachable testing in 4 % acetic acid at 22 °C for 24 hours
- ✓ the end sealing's materials of construction comply with the relevant migration requirements of Commission Regulation (EU) 10/2011 of January 14th, 2011, as amended, "on plastic materials and articles intended to come into contact with food" for all food types

- **EASTERN EUROPE**

TAMI Ceramic Membranes are approved by the National Russian Institute of food N° 0412 417

TAMI Ceramic Membranes and gaskets are approved by the National Polish Institute of Hygiene/Department of Food Research N° 04/HT/99.

- **USA**

The membranes material of construction are listed in the FDA requirements for food contact use as detailed in 21 CFR paragraphs 170-199 in that:

- ✓ Titania is listed in 21 CFR 178.3297 and approved as an indirect food additive
- ✓ Zirconia is listed in 21 CFR 177.2910, for materials coming into contact with food products.

The end sealing's materials conform to US Food and Drugs Administration (FDA), document 21 CFR paragraph 175.300 for food contact.

TAMI USDA housings conform to 3-A Sanitary Standards (section 45-02).

MEMBRANES' GASKETS

The chemical composition of TAMI gaskets (VITON and HNBR) are made from components complying with:

- US Food and Drugs Administration (FDA), document 21 CFR paragraph 177.2600 for elastomer

The chemical composition of TAMI gaskets (EPDM, SILICON and FFKM) are made from components complying with:

- European food Regulations (EC) Number 1935/2004,
- US Food and Drugs Administration (FDA), document 21 CFR paragraph 177.2600 for elastomer,
- French decree of November 9th, 1994 relating to rubber materials and objects in contact with foodstuffs, food products and drinks, amended by decree of December 19th, 2006,
- French decree of November 25th, 1992 relating to silicone elastomer materials and objects in contact with foodstuffs, food products and drinks,

These products are also manufactured according to the directive for GMP 2023/2006/EC.

TAMI gaskets are free from ingredients derived from animal substances and are therefore free from bovine spongiform encephalopathy (BSE) and transmissible spongiform encephalopathy (TSE). They are also free of phthalates, bisphenol A and latex.

Quality Certification

The TÜV Rheinland France certifies TAMI INDUSTRIES NYONS to ISO9001:2015 Certificate N° MS10ISO9K 10482 / IDn°9105047253.

The TÜV Thüringen certifies TAMI Deutschland Hermsdorf/Thüringen to ISO9001:2015 Certificate N°TIC15100169625 / ABn°33302R7PA0.

Products are identified either by lot numbers or individual codes in order to obtain complete traceability.

Users should satisfy themselves that these materials are suitable for use in their specific food application