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Sterilization Statement

Date of issue: Jul 28, 2026

To whom it may concern:

We, the manufacturer, declare that our flange products and the items made of polypropylene and silicone mentioned below can be sterilized in the microwave steam bags, boiling water or autoclave 121 degrees Celsius for 15 minutes.

Product SKU (Model Number):

Polypropylene (PP) Products:

A012-Fxx, A012-B, L012W-B, MP012C-Fxx, MP012-Fxx, M012-B, M012-tB, M012-Fxx, S012W-Fxx, S012W-B, S012W.2G-B

Note: "xx" represents the size of the flanges. Packs of multiple units are not listed, but their nomenclature follows the same prefix.

Silicone Products:

M003-M, S005.40-D, A005-D, E005-D, L005-D, P005.2G-D, XP024-M, F012-i##, F012.2G-i##, X012-i##, X012.2G-i##, S112-i24x2, E012-i##, E012-i##.g, E012-i##.m, E012-i##.b.

Note: In a model no., the number (##) refers to the internal diameter in mm at the entrance of the nipple tunnel of an insert. The letter **g** stands for green; **m** stands for magenta; **b** stands for blue.

Polypropylene (PP) and Silicone Products:

M005-2V4M, M005-4V6M

We have done autoclave study on our flanges/shields as the report below.

Reference: report #. TWNC00596197

URL: <http://www.maymom.com/en/reports/TWNC00596197%20autoclave.pdf>

All the polypropylene products mentioned above use the same material so they can fall into the same category as what is on the report.

FDA-compliant reports for our silicone-based products indicate a significantly higher melting point compared to polypropylene. Since the product launch, we have not received any customer feedback regarding damage to the silicone products from steam-based sterilization. Therefore, we recommend using the same autoclave conditions for these products.

An autoclave set at 121°C, 14.2 psi, for 15 minutes is internationally accepted as effective in sterilizing materials by killing most bacteria and viruses. This temperature and pressure combination represents a standard sterilization cycle.

When cleaned and reprocessed according to validated sterilization procedures, the above-listed products may be reused across multiple users.*

*** Important Notes:**

- While we, the manufacturer, provide guidance on sterilization methods and compatible materials, we do not and cannot guarantee the effectiveness of the sterilization process itself, as it is highly dependent on factors outside our control — including equipment performance, human error, process consistency, and environmental conditions.
- The healthcare provider or designated reprocessing personnel are fully responsible for ensuring proper cleaning, inspection, and sterilization of the product prior to each use.
- The sterilization information in this statement applies to sterilization only. For detailed cleaning and preparation instructions, please refer to the applicable instructions for use (IFU) for each product.

Autoclave Sterilization Parameters:

- Temperature, Pressure and Time Length: 121 degrees Celsius, 14.2 psi, 15 min for the sterilization process
- Drying time after sterilization: This parameter varies depending on the model and make of the sterilizers and local practices. Follow your cleaning room's practice.

Should you have any questions regarding to this statement, feel free to contact us.

Name: Liangchi Li

Function: Manager of Maymom LLC

Signature:

A handwritten signature in blue ink, appearing to read "Liangchi Li", is written over a light blue rectangular background.