No. 580 Autoclavable Mat

COMPLIANCE

The Autoclavable Mat No. 580 complies with USP 797 CSP Risk Levels

USP 797 - Risk levels are assigned to CSPs on the basis of their potential for microbial contamination.

Low Risk – a one to one mix ratio. A good example of this is the transfer of a compound into a syringe or a mini-bag.

Medium Risk – An ISO Class 7 Clean room, formerly a Class 10,000 Clean room where three or more ingredients are mixed in 1 to 3 or 3 to 1 ratios.

High Risk - An ISO Class 5 Clean room requiring laminar-flow workbenches or barrier isolators. The creation of any CSP using nonsterile ingredients or CSPs that require filtration, steam, heat gas or ionizing radiation, are considered high-risk operations. High-risk areas must be totally accurate and sterile, devoid of living microorganisms. Any mats used in these areas will need to be autoclaved or cleaned with a very stringent sterilizing agent such as:

- 3% hydrogen peroxide
- 1-2% bleach solution
- Glutaraldehyde – recommended for use on plastics and rubber
- Quaternary Ammonium compounds (QUATS) – ordinary housekeeping

Wearwell[R]'s Autoclavable Mat has passed the rigorous ASTM test used by NSF to determine Resistance to Microorganisms.

The NSF specifies "Supplemental flooring materials shall be resistant to microbial action and shall not contribute to or support survival or growth of microorganisms when tested in accordance with ASTM G21-96 (2002)". * This rigorous test exposes each sample of the mat compound to Aspergillus niger ATCC[3] 9642, Penicillium pinophilum ATCC 11797, Chaetomium globosum ATCC 9645, Gliocladium virens ATCC 9645, and Aureobasidium pullulans ATCC 15233. To test the possibility of growth, the samples are exposed to these organisms and then incubated at 82 to 86 degrees F and 85% humidity for 28 days.

In order for the compound to **pass NSF** with a **Rating I**, there cannot be more than traces of growth on the samples. The Autoclavable Mat showed **no traces of growth**. According to NSF specs, this more than meets a **Rating I**.

NORTH AMERICA
WEARWELL, INC. (HEADQUARTERS)
PHONE: 615.254.8381 OR 1.800.264.3030
INFO@WEARWELL.COM
WWW.WEARWELL.COM

UK & IRELAND
WEARWELL EUROPE LTD
PHONE: 44.1844.212117
INFO@WEARWELL-EUROPE.CO.UK
WWW.WEARWELL.EU

MAINLAND EUROPE
WEARWELL EUROPE LTD
PHONE: 31.548.659061
EUROPE@WEARWELL.EU
WWW.WEARWELL.EU