

**Corning Incorporated
Life Sciences**

Registered
ISO 9001:2008

Product Description

Catalog Number: 3781

Product Description: Synthemax® II microcarriers; low concentration, 10g vial, sterile

Product Dimensions:

Microcarrier Diameter Range	-	125-212 µm	Weight per vial	-	10 grams
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Component Materials:

Beads	-	Polystyrene, meets <i>USP, Class VI</i> requirements for plastic containers and closures.
Surface	-	Proprietary Peptide Acrylate chemistry.
Peptide Density	-	3pMol/mm ²
Relative Density	-	1.022-1.030 vs H ₂ O

Sterilization:

The lot has been irradiated and dosimetrically released based on ANSI/AAMI/ISO 11137 *Sterilization of health care products-Requirements for validation and routine control-Radiation sterilization*.

Sterility Assurance Level: SAL 10⁻⁶

Pyrogens:

The product has been tested and has met the criteria established in the current version of ANSI/AAMI ST 72:2002/(R)2010 *Bacterial Endotoxins - Test methodologies, routine monitoring, and alternative to batch testing*. Results: ≤ 0.1 EU/mL (≤ 4EU/device)

Bovine Spongiform Encephalopathy and Transmissible Spongiform Encephalopathy:

This product complies with the latest version of EMEA 410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human veterinary products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMEA/410/01.

Surface Characterization:

The surface is coated with a proprietary synthetic peptide acrylate optimized for stem cell expansion.

Cell Attachment and Growth Characteristics:

The product has been tested for the attribute of stem cell attachment and growth.

Performance Testing:

Each manufacturing lot is sampled and tested in accordance with Standard Operating Procedures.

Visual Attributes:	Visual and microscopic examination of the product.
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Packaging:	Inspection for seal and barrier integrity, accurate labeling, and correct product configuration.
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Peptide Density:	Bicinchoninic Acid protein assay procedure
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Lot Number Designation:

8 Digit Lot Number: First 3 digits - Julian date, start of manufacturing; Next 2 digits - Year of manufacture; Last 3 digits - Batch identification.

Rev No: 2