

Catalog Number: 4623

Product Description: Corning Low Concentration Synthemax® II Microcarriers, 500g, Sterile

Component Materials:

Beads - Polystyrene, meets *USP Class VI requirements for plastic containers and closures.*
Relative Density - 1.022-1.030 vs H₂O

Product Dimensions:

Microcarrier Diameter - 125-212 µm Weight per 850cm² Rollerbottle - 500 grams

Animal Content - Product does not contain materials of animal origin.

Non – Pyrogenic - Tested and met the criteria established in the current version of ANSI / AAMI ST 72, “Bacterial Endotoxins - Test methodologies, routine monitoring, and alternatives to batch testing”. The acceptance level for product is ≤ 0.10 EU/ml or ≤ 4 EU / device.

Sterilization - Product has been sterilized and dosimetrically released per the requirements of ANSI /AAMI / ISO 11137, “Sterilization of health care products – Radiation”. Products meet a minimum Sterility Assurance Level (SAL) of 10⁻⁶.

Surface Characterization – The surface is coated with a proprietary synthetic 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.

Peptide Density – Peptide Density is measured using a Bicinchoninic Acid Protein Assay. Peptide Density ≥ 3pMol/mm².

Quality Control Testing – Representative production samples are collected and inspected in accordance with applicable product specifications. Inspection records are reviewed and approved by qualified personnel for product release. Key inspections and inline tests are listed below:

Visual Inspection	-	Pass
Packaging Inspection	-	Pass
Bicinchoninic Acid Protein Assay-		Pass

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: 1