

Corning Incorporated - Life Sciences
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Refer to website for regional contact information.

Page: 1 / 1

Product Name : SYNTHEMAX II - SC SUBSTRATE	
Catalog Number : 3535	Manufacture Date : 2020-01-08
Lot ID : 00820009	
Expiration Date : 2022-01-07	

Quality Management System - Complies with the current version of the ISO 9001 Standard and the FDA CFR 21 Part 820, current Good Manufacturing Practices (cGMP).

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

USP Class VI Testing - All material resin is tested, qualified and shown to be non-toxic as established in the Standards USP Class VI Chapter<87>, "Biological reactivity Tests, in Vitro" and Chapter<88>, "Biological Reactivity Tests, in vivo".

Sterility - 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^{-3} .

Product Attribute - Product designed to promote the growth and attachment of Mesenchymal stem cells.

Quality Control Testing - Representative production samples are collected and inspected in accordance with current 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
- Peptide Density - Pass
- Packaging Inspection - Pass

- This product met Corning Incorporated - Life Sciences' high standards of quality at the time of batch/lot release.



Jason Jens
Plant Quality Manager