Corning Incorporated Life Sciences

Registered ISO 9001:2008 **Product Description**

Catalog Number: 4571

Product Description:	Corning® 1536WL, ti labels	${f Corning}$					
Component Materials	3:						
Plate -		Cyclic Olefin Co-polymer, meets USP, Class VI requirements for plastic containers and closures. White cyclic olefin co-polymer concentrate					
Barcode label		White polypropylene base, acrylic adhesive.					
Special Feature Barcode label (format	128) on A1 long side and H12	2 long side					
Product Dimensions:	- 5.030 in.	Width of Square Well @ Top - 067 in					

Length of Plate	-	5.030 in.	Width of Square Well @ Top	-	.067 in.
Width of Plate	-	3.365 in.	Width of Square Well @ Bottom	-	.060 in.
Depth of Well	-	.195 in.	Height without Lid	-	.409 in.
Tolerances of Dimensions	-	+/010 in.	Working Volume	-	8µl
Maximum well volume	-	13µI	Tolerance of Dimensions for	-	+.010 in /015 in.
			Lenath		

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.

Surface Characterization – Surface is characterized to be hydrophilic and negatively charged. The negatively charged, carboxyl surface composition, has been optimized for cell attachment and growth.

Optical Characteristics – The product is made of opaque white cyclic olefin co-polymer walls to minimize the well to well crosstalk and background fluorescence and / or luminescence.

BSE/TSE – Product complies with the latest revision of EMA/410/01 "Note for Guidance on minimizing the risk of transmitting animal spongiform encephalopathy agents via human and veterinary medicinal products" by virtue of all bovine derived material having been processed per specific conditions of section 6.4 of EMA/410/01.

Tissue Culture – Tested for the attribute of cell attachment and growth utilizing an attachment-dependent mammalian cell line. Cell attachment within 24 hours is required for acceptance.

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.

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 Packaging Inspection – Pass Cell Attachment & Growth Treatment Verification – 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.