

Viresolve® Pro Modus 1.1 Device

Catalogue Number: VPMD101NB1

Lot Number: C9CN82433

Good Manufacturing Practices

This product was manufactured in a Millipore facility which adheres to Good Manufacturing Practices.

ISO® 9001 Quality Standard

This product was manufactured in a Millipore facility whose Quality Management System is approved by an accredited registering body to the appropriate ISO 9001 Quality Systems Standard.

Gamma-Irradiation

This product has been gamma irradiated with a dosage of 6-10 kGy prior to shipment.

Animal Origin Statement

All component materials used in the manufacture of this device are either animal free or in compliance with EMEA/410/01.

100% Manufacturing Integrity Test

Each unit must pass the Millipore Binary Gas Test.

Each unit exhibited an air diffusion flow rate of less than or equal to 0.7cc/min per device at 50 psig (3.4 bar) in water at 25° C.

Component Materials Toxicity

Component materials were tested and meet the Criteria for the USP <88> Biological Reactivity Tests for Class VI Plastics.

Non-Fiber Releasing

This product was manufactured with products that meet or exceed the criteria for "Non-fiber releasing filler" as defined in 21 CFR 210.3(b)(6).

European Pressure Equipment Directive

Millipore Corporation certifies that this product complies with the European Pressure Equipment Directive, 97/23/EC of 29 May 1997. This product has been classified under Article 3 § 3 of the Pressure Vessel Directive. It has been designed and manufactured in accordance with sound engineering practice to ensure safe use. In compliance with Article 3 § 3 of this Pressure Equipment Directive, this product does not bear the CE mark.

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Quality Assurance Lot Release Criteria

This manufacturing lot was sampled, tested and released by Quality Assurance to the following specifications:

USP Bacterial Endotoxins

A sample aqueous extraction contains less than 0.25 EU/ml as determined using the Limulus Amebocyte Lysate (LAL) test.

Membrane Bacteriophage Retention Test

Samples of the Viresolve Pro membrane exhibited equal to or greater than 4 LRV retention of ØX174 bacteriophage in the presence of a model protein at a minimum challenge level 10⁷ pfu/cm².

Device Bacteriophage Retention Test

Device samples exhibited equal to or greater than 4 LRV retention of ØX174 bacteriophage at a minimum challenge level 10⁷ pfu/cm² after gamma irradiation at 6-10 kGy.

Hydraulic Stress Test

Samples were tested for air/water diffusion before and after a forward stress to 60 psid (4.1 bar) at 25° C.

TOC and Conductivity

Effluent exhibited less than 500 ppb TOC per USP <643> and less than 1.3 µS/cm conductivity per USP <645> after gamma irradiation (1 cycle of 6-10 kGy dosage) and after a water flush of 100 L/m².

Quality Performance Criteria

This product was designed and manufactured to meet the following specifications.

Toxicity

This product is nontoxic per USP Cytotoxicity MEM Elution Test.

Peter Eichert
Quality Manager

