M.S.D.N: 0316947580 - C.T.T.N.H.H
CÔNG TY TNHH NIPRO SALES VIỆT NAM
THÀNH PHỐ HỒ CHÍ MINH

NIPRO CORPORATION ODATE FACTORY
8-7, Hanukiyachi, Niida, Odate-Shi, Akita 018-5794, Japan
Phone: +81-186-49-5111 Facsimile: +81-186-49-3944

Date: July 26, 2016

To whom it may concern;

DECLARATION

We, Nipro Corporation Odate Factory, hereby declare that attached documents are the **Technical and Physical Specifications** for Nipro Ultra Filter CF-609N.

Sincerely Yours,

T. Kaneya

T. Kaneya
Manager
Quality Assurance Section III
Quality Assurance Department
Nipro Corporation Odate Factory

Appearace and Functional Tests

(The order of the tests is not specified since individual sample is used for each test.)

Inspection/test item (Defect classification)	Criteria	Level	Inspection / test frequency	Inspection/test method
(Critical defect: Package: AQL =4.0) (Critical defect: Product: AQL =0.10) (Major defect: AQL = 0.65) (Minor defect: AQL = 1.0)				Perform the sampling inspection according to ANSI/ASQ Z1.4 Single Sampling Plan Special Inspection Level S-2 and General Inspection Level II
1. Appearance inspection				
1-1 Packing box (outer and inner boxes)			Each product code or lot	Check the relevant product visually about absence/presence of defects described on the left.
Different model mixed in (Critical)	Shall not occur.	S-2		
Wrong indication or no indication (Critical)	Shall not occur.	S-2		
Significant dirt or damage (Critical)	Shall not occur.	S-2		
Illegible printing (Critical)	Shall not occur.	S-2		
Chemical indicator color check (Critical)	Shall be red.	S-2		
Packaging specifications (Indication, printing, etc.) (Critical)	Shall follow the drawing specifications.	S-2		
1-2 Product				
Human hair, bug in package (Critical)	Shall not occur	II	Each product code or lot	
Package torn, defective seal (Critical)	Shall not occur	II		
Mismatched indication, different model mixed in (Critical)	Shall not occur	II		
Insufficient quantity (Critical)	Should contain specified quantity.	II		
Printing (Critical)	Shall be printed.	II		
Label, antioxidant and cap (Critical)	Shall have it.	II		
No cut end (Major)	Shall have it	II		
Dirt on package	Shall not occur	II		
Illegible printing (Major)	Shall be legible	II		
Misalignment of printing (Minor)	Shall be printed on appropriate positions.	II		
(Critical defect AQL=2.5) 1-3 Product/ Gamma sterilized product				Perform the sampling inspection according to ANSI/ASQ Z1.4 Single Sampling Plan Special Inspection Level S-1.
Printings on label is checked. (Critical)	It shall conform to Print Instruction Record.	S-1	Each product code or lot for each destination.	
Product specification is checked. (Critical)	It shall conform to drawing.	S-1	Should be same as drawing	

Technical Specification(Nipro Ultra Filter CF-609N)

Inspection/test item (Defect classification)	Criteria	Level	Inspection / test frequency	Inspection/test method
(Critical defect :AQL=1.5)				Perform the sampling inspection according to ANSI/ASQ Z1.4 Single Sampling Plan Special Inspection Level S-1.
2. Functional test (Critical)				
2-1 Leakage from packaging film	Shall not leak, and the product shall be easily taken out when package is opened after the test.	S-1	Each product code or lot	Pressurize with a compressor until inner pressure of the package becomes 74 mmHg (9.8 kPa). Then open the package and take out the product.
2-2 Protein stopping ratio	Insulin 90% or more	S-1	Every time when manufacturing condition is changed.	Follow the Performance Evaluation Method of Membrane 2. Sieving Coefficient Assay (water system) specified by High Performance Membrane Study Group.
2-3 Initial permeability	≧300 [mL/hr/mmHg]	S-1	Each product code or lot	Perform the inspection in accordance with Standards for Performance Evaluation of Dialyzers II UFR Measuring Method 1.Single Pass Method(4) C method (STOP method).
2-4 Dialysate concentration test	The difference in concentrations of Na, Cl, acetic acid, glucose and osmotic pressure shall be 90% or more before and after the filtration.	S-1	Every time when manufacturing condition is changed.	Follow Safety and Performance Tests Guideline (Projection) of Endotoxin filter for dialysate.
2-5 Water leakage	No air bubble shall be allowed.	S-1	Each product code or lot	Observe the dialyzer while applying air pressure of 1.5 kgf/cm^2 (147 kPa) to blood compartment.
2-6 Ink leakage	No ink leakage shall be allowed.	S-1	Each product code or lot	Add 5 times diluted ink to the dialysate compartment. Then observe the urethane cross section while applying air pressure of 0.2 kgf/cm^2 (19.6kPa) to dialysate compartment after.
2-7 Pressure-resistant	Shall no leak	S-1	Every time when manufacturing condition is changed.	By using ion-exchanged water (PVP solution), adjust TMP of dialyzer to 1.0(0.7)kgf/cm≒98(68.6)kPa and and observe it after circulation for 6(12) hours.

Technical Specification(Nipro Ultra Filter CF-609N)

Inspection/test item (Defect classification)	Criteria	Level	Inspection / test frequency	Inspection/test method
(Critical defect AQL=2.5) 2-9 Product/ Gamma sterilized product				Perform the sampling inspection according to ANSI/ASQ Z1.4 Single Sampling Plan Special Inspection Level S-1.
Printings on label is checked. (Critical)	It shall conform to Print Instruction Record.	S-1	Each product code or lot for each destination.	Check the relevant product visually about absence/presence of defects described on the left.
Product specification is checked. (Critical) * When they are conducted at functional check, it is not necessary.	It shall conform to drawing.	S-1	Should be same as drawing	

Safety test, sterility

Inspection/test item (Defect classification)	Criteria	Level	Inspection / test frequency	Inspection/test method
Safety test, sterility 3. Physicochemical test (Critical) 3-1 Eluted substance test of dialysis membrane		1 Fiber	Each product code or lot	Follow Safety and Performance Tests Guideline (Projection) of Endotoxin filter for dialysate.
(1) Appearance	Clear and colorless, no foreign material			
(2) pH	Difference from blank test liquid: 1.5 or less			
(3) Foaming	Shall disappear within 3 minutes.			
(4) Zinc	0.5 µg/mL or less			
(5) Copper	1.0 µg/mL or less			
(6) UV absorption spectrum	Difference from blank test liquid: 0.1 or less			
3-2 Eluted substance test of follow fiber adhesive part	Difference from blank test liquid 0.05 or less	10g	Each product code or lot	
4. Biological test(Critical) (1) Pyrogen test		1 pc	Once a month	Follow Safety and Performance Tests Guideline (Projection) of Endotoxin filter for dialysate.
	Shall be negative			
(2) Acute toxicity test	Shall be no abnormalities or deaths			
(3) Hemolysis test	Shall be less than 0.5%.			
(4) Intracutaneous reactivity test	Shall be no erythema, edema, bleeding, necrosis, etc.			

Technical Specification(Nipro Ultra Filter CF-609N)

Inspection/test item (Defect classification)	Criteria	Level	Inspection / test frequency	Inspection/test method
5. Endotoxin stopping power test (Ctirical)	Stopping ratio shall be 99% or more.	1 pc	Every time when manufacturing condition is changed.	Follow Safety and Performance Tests Guideline (Projection) of Endotoxin filter for dialysate.
6. Sterility (Critical) ・ Measurement of absorbed radiation	Validated dose or more.	-	Per sterilization lot	Measure absorbed dose of a dosimeter attached to a product carton.