



ENDOTOXIN FILTER (CF-609N)

DIALYSIS FLUID ULTRA FILTER FOR THE REDUCTION OF ENDOTOXINS,
BACTERIA, AND PARTICLES



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DIALYSIS FLUID ULTRA FILTER FOR THE REDUCTION OF ENDOTOXINS, BACTERIA, AND PARTICLES

- The removal of endotoxins, bacteria, and particles larger than 6000 Dalton
- Compatible with all models of Surdial™ X and Surdial™ 55Plus
- PES membrane withstands high pressure resistance of 1,5 kgf/cm²
- Three port caps with easy twist removal

CE 0123

Class IIa Medical Devices

Rule 3

MDD 93/42/EEC

Product Compliance

- Complies with the following norms, directives, and regulations:
 - ISO-8637-1: 2017
 - ISO-10993-1: 2018
 - ISO-10993-3: 2014
 - ISO-10993-4: 2017
 - ISO-10993-5: 2009
 - ISO-10993-10: 2013
 - ISO-10993-11: 2018
 - ISO-11137-1: 2006
 - ISO-11137-2: 2015
 - ISO-11137-3: 2017
 - EN-556-1: 2006

Manufacturing DETAILS

Legal manufacturer: NIPRO CORPORATION

Country of origin: Japan

Sterilization and Shelf Life

Sterilization

Gamma ray



Indicator sticker

"Each outer box (or shipping carton) contains a chemical indicator that ensures sterility. This indicator comes in the form of a yellow sticker that turns red when sterilized."

Shelf life

3 years



Materials Used



Specifications

**Not made with
Latex, PVC**

Effective surface area (m ²)	0,6 m ²
Membrane thickness (µm)	150 µm
Hollow fiber inner diameter (µm)	500 µm
Hollow fiber outer diameter (µm)	800 µm
Maximum operating pressure	1,5 kgf/cm ²
High water permeability and pressure loss	0,07 kgf/cm ² (at 37°C and 500 mL/min) 0,14 kgf/cm ² (at 37°C at 1000 ml/min)
Molecular weight cut-off point	6000 Dalton
Logarithmic reduction value (LRV) for bacteria	> 8,0 (10 ⁻⁸)
Logarithmic reduction value (LRV) for endotoxins	> 4,0 (10 ⁻⁴)
Lifetime (ref: Surdial™ X and Surdial™ 55Plus disinfection)	Citric acid disinfection: maximum 1800 hours Peracetic acid disinfection: maximum 1200 hours Sodium hypochlorite disinfection: 30 disinfections

PRODUCT RANGE OVERVIEW

Reference code	EAN-13	GTIN-14 Outer box	GMDN code	Custom code
CF-609N-GJ	5420040802009	45420040802007	47739	84212980

Packaging Details

Reference code	Individual unit (pouch)				Inner box				Outer box					
	L (cm)	W (cm)	H (cm)	Weight (kg)	Quantity (pcs)	L (cm)	W (cm)	H (cm)	Weight (kg)	Quantity (pcs)	L (cm)	W (cm)	H (cm)	Weight (kg)
CF-609N-GJ	44	16	1,35	0,275	1	35,5	16	7	0,465	12	50	37	31,1	5,95

Languages

1 language on individual unit label: English (EN)

16 languages on IFU, pouch label, inner box, and outer box:

English (EN), German (DE), French (FR), Spanish (ES), Italian (IT), Dutch (NL), Portuguese (PT), Greek (EL), Swedish (SV), Danish (DA), Norwegian (NO), Finnish (FI), Russian (RU), Czech (CS), Turkish (TR), and Ukrainian (UK)

Transport conditions

Avoid direct exposure to sunlight, as well as excessive humidity, dryness, and vibration.

Storage conditions

Store between 0 to 35°C.

Label details

	Individual unit	Pouch	Inner box	Outer box
Product name	✓	✓	✓	✓
Quantity (pieces)	—	—	✓	✓
	—	—	—	✓
	✓	✓	—	✓
	✓	✓	—	✓
	✓	✓	—	✓
	✓	✓	—	✓
	✓	✓	✓	✓
	✓	✓	—	✓
	✓	✓	—	✓
	✓	✓	✓	✓
	✓	✓	✓	✓
	—	—	—	✓
	—	—	—	✓
	—	—	—	✓
	—	—	—	✓
	—	—	✓	✓
	✓	✓	—	✓