



## DEVICE DETAILS

<b>NAME OF DEVICE</b>	U9000 PLUS ULTRAFILTER
<b>ESTABLISHMENT NAME</b>	BAXTER HEALTHCARE (MALAYSIA) SDN. BHD.
<b>REGISTRATION NO</b>	GC3416521-73508
<b>DESCRIPTION</b>	<p>The U9000 Plus Ultrafilter is intended to be used as system components with Baxter /Gambro /Hospal dialysis monitor platforms (AK 98 and Artis/Evosys). Ultrafilter U9000 Plus is connected to the dialysis fluid circuit in a dedicated holder before it reaches the dialyzer. The hollow fibers are potted at each end in polyurethane to separate the two compartments (i.e., feed and filtrate side). Water or dialysis fluid enters the feed side port where it is distributed to the hollow fibers. By means of hydrostatic pressure or transmembrane pressure, water or dialysis fluid passes through the membrane into the filtrate compartment of the device. The membrane retains bacteria and endotoxins. With Artis/Evosys, the purified dialysis fluid leaving the device through the filtrate exit can be used to prepare online infusion fluid after additional filtration. The U9000 Plus Ultrafilter is delivered as non-sterile devices and need to be disinfected after installation on the dialysis machine before it can be used to prepare purified water. After installation, U9000 Plus Ultrafilter becomes an integral part of the dialysis fluid flow path of the dialysis machine; all machine processes that involve the Ultrafilter (e.g., dialysis fluid preparation, disinfection, rinsing) are controlled by the dialysis machine.</p>
<b>DEVICE GROUPING TYPE</b>	Single
<b>INTENDED PURPOSE</b>	<p>The U9000 Plus Ultrafilter is indicated for purification of incoming water for dialysis fluid as well as purification of dialysis fluid to obtain microbiologically high quality dialysis fluid*. The risk of exposure to bacteria and endotoxins can thereby be minimized. The U9000 Plus Ultrafilter is intended to be used in conjunction with a water treatment system. Warning: The U9000 Plus Ultrafilter can only be used with Gambro/Baxter/Hospal dialysis machines equipped with holder for an ultrafilter.</p>
<b>VALIDITY DATE OF REGISTRATION</b>	23-09-2021 - 22-09-2026

## LIST OF DEVICE

#	NAME OF DEVICE	IDENTIFIER
No results found.		