REVERSE OSMOSIS

Culligan®

Aqua-Cleer®

RO² MD BiO E

DOUBLE PASS **REVERSE OSMOSIS**

CE MARKED AS **CLASS IIb** MEDICAL DEVICE ACCORDING TO MEDICAL DEVICE DIRECTIVE 93/42/EEC

DOUBLE PASS **REVERSE OSMOSIS**

The Culligan **RO² MD BiO E** is Culligan's most technologically advanced water treatment system for haemodialysis utilizing the latest in bi-osmosis water treatment technology.

The **RO² bi-osmosis** system consists of two separate reverse osmosis systems operating in series to produce water of the highest quality and purity.

By operating in series the system effectively treats the water twice. In the first pass, 90-99% of the salts and other contaminants in the water are removed, and in the second pass, again an additional 90-99% of the residual contaminants are removed.
Most importantly this provides a guaranteed barrier to microbial contamination.

An added advantage to the **Culligan bi-osmosis system** is that in the event of an emergency, the system can operate on a single reverse osmosis system and still produce dialysis quality water.

The Culligan **RO²** will automatically move to this single pass configuration in the unlikely event of a problem, so there is no need for manual intervention.

- CLASS IIb
- FLOWS UP TO 4400 L/H
- ADVANCED SAFETY SYSTEMS
- FULLY ELECTRONIC
- NOTIFIED BODY NO. CE 0434
- 4 MODELS AVAILABLE

Aqua-Cleer® **RO²** MD **BiO** E

RO² ▶ **Double Pass RO** treatment for the highest quality and safest water for dialysis.

MD ▶ CE marked as **Class IIb** Medical Devices according to **Medical Device Directive** 93/42/EEC DEVICE DIRECTIVE 93/42/EEC

BiO ▶ **Bi-Osmosis** for the highest quality water Built with **Biocompatible materials**.

E ▶ **Electronic** - Advanced PLC control.
Efficient - Maximum water recovery.

1-2-3-4 ▶ **4 Models** with capacities from 730 to 3200 l/h (from 3.2 to 14.1 GPM) always in 2-pass Bi-osmosis.

MEDICAL DEVICE QUALITY SYSTEM CERTIFIED
ACCORDING TO **UNI EN ISO 13485** & **93/42/EEC**

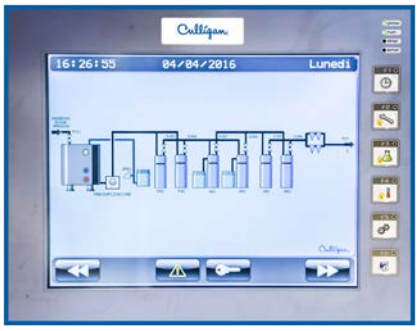
AVAILABLE MODELS FOR AQUA-CLEER® **RO²** MD **BiO E**

Models	Flow l/h*(GPM)	Installed Power kW (HP)	Dimensions width. x depth. x height. mm (inches)
RO² MD **BiO** 1 E	1000 (4.4)	2x3 (2 x 4 HP)	1800x800x1900 (70 x 31 x 75 inches)
RO² MD **BiO** 2 E	1500 (6.6)	2x3 (2 x 4 HP)	1800x800x1900 (70 x 31 x 75 inches)
RO² MD **BiO** 3 E	2500 (11)	2x4 (2x5.4 HP)	1800x800x1900 (70 x 31 x 75 inches)
RO² MD **BiO** 4 E	4000 (17.6)	2x4 (2x5.4 HP)	1800x800x1900 (70 x 31 x 75 inches)

* Note : Flow rates shown relate to new membranes operating on properly pretreated feed water of 500 mg/l TDS, 20 °C

All of the **Aqua-Cleer® RO² MD BiO E** models are **PLC controlled**

Simple and intuitive **"touch screen"** interface with advanced controls.



Dynamic views

- Inlet to Reverse Osmosis conductivity
- Conductivity of water produced by 1st stage RO
- Conductivity of water produced by 2nd stage RO
- Flow rate of RO water produced by 1st stage RO
- Flow rate of RO water produced by 2nd stage RO
- Flow rate of reject water produced by 1st stage RO
- Flow rate of reject water produced by 2nd stage RO
- Flow rate of water returning from dialysis loop
- Flow rate and consumption rate of artificial kidneys
- RO 1st stage operating pressure
- RO 2nd stage operating pressure
- Inlet to Reverse Osmosis temperature
- Distribution loop temperature
- REDOX meter reading

Graphic views

- Graphical trending of conductivity
- Graphical trending of system flow rates
- Graphical trending of system temperature
- Historical archives of operating data
- Immediate display of error messages

Culligan's bi-osmosis water treatment equipment is the result of 30 years of experience in the haemodialysis sector.
The new Bi-Osmosis system is Class IIb Certified and is medical device certified according to
UNI EN ISO 13485, and CE 0434.

Culligan is committed to environmental sustainability and has designed the new RO² system to be as energy- and water-efficient as possible. By offering a modular design with a range of flow rates and by recycling and retreating as much water as possible, the new **RO²** MD BiO **E** water treatment system can help reduce utility costs and meet environmental commitments.

Culligan®

WATER QUALITY AND DIALYSATE GUIDELINES & CULLIGAN CERTIFICATES

Chemical contaminants

Category		Parameter	Measure unit	Monitoring place and maximum acceptable level	
				Raw water (yearly frequency) Max level	Dilution water (every 6 months) Max level
1) Natural source	Inorganic:	Calcium	mg/L		2
		Chloride	mg/L	250	50
		Hydrogen ions	Unità pH	6.5 ÷ 9.5	4.4 ÷ 7.5
		Fluoride	mg/L	1.5	0.2
		Magnesium	mg/L		2
		Potassium	mg/L		2
		Sodium	mg/L	200	50
		Sulphate	mg/L	250	50
2) Anthropogenic	Inorganic:	Mercury	mg/L	0.001	0.001
		Lead	mg/L	0.01 (0.025 up to 25/12/2013)	0.1
		Nitrates (as NO_3)	mg/L	50	2
		Ammonium	mg/L	0.5	0.2
	Organic:	Total organo-alogenated compounds	µg/L	30	30
3) Products used for potabilisation	Inorganic:	Aluminium	mg/L	0.2	0.01
		Total Chlorine	mg/L	0.2	0.1
4) Byproducts for potabilisation treatment	Inorganic:	Zinc	mg/L		0.1
	Organic:	Total THM	µg/L	30	30

Note: these data refer to Italian Pharmacopoeia

Microbiological controls

Test	Raw water		Treated water		Regular dialysate		Ultrapure dialysate	
	Reference value	Frequency	Reference value	Frequency	Reference value	Frequency	Reference value	Frequency
UFC/mL Bacteria at 22 °C	< 100	every 6 months	< 100	monthly	< 100	every 4 months in each display	< 0.1	every 2 months in each display where online treatments are effected
Molds and Yeasts /mL	-	-	< 10	every 6 months	< 10		0	
Endotoxins UI/mL	-	-	< 0.25	monthly	< 0.25		< 0.03	

EC CERTIFICATE

FULL QUALITY ASSURANCE SYSTEM for WATER TREATMENT DEVICE FOR HAEMODIALYSIS

DNV BUSINESS ASSURANCE

EC CERTIFICATE - FULL QUALITY ASSURANCE SYSTEM

Certificate No. 74676-2010-CE-ITA-NA 4.0
This Certificate consists of 3 pages

This is to certify that the Quality Management System of

CULLIGAN ITALIANA SPA

Italy

for design, production and final product inspection/testing of

Water Treatment Device for Haemodialysis

has been assessed with respect to

the conformity assessment procedure described in Article 11.3.a and Annex II excluding section 4 (Module H) of Council Directive 93/42/EEC on Medical Devices, as amended, and found to comply

Further details are given overleaf

Place and date: Høvik, 16 November 2015 — *This Certificate is valid until:* 05 October 2020

For DNV GL BUSINESS ASSURANCE NORWAY AS

Aud Lukon Eikhil, *Certification Manager* — Notified Body No.: 0434 — Angela Lanna, *Technical Reviewer*

This Certificate has been digitally signed. See www.dnvgl.com/assurance for more info.

Notice: The certificate is subject to terms and conditions overleaf. Any significant changes in design or construction may render this certificate invalid.

DNV GL Business Assurance AS, Veritasveien 1, 1322 Høvik, Norway. Tel: +47 67 57 99 00 Fax: +47 67 57 99 11 www.dnvgl.com

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UNI EN ISO 13485:2004

QUALITY MANAGEMENT SYSTEM

DNV·GL

MANAGEMENT SYSTEM CERTIFICATE

Certificate No. / Certificate No.: 12509V-2012-AQ-ITA-ACCREDIA — Data prima emissione/Initial date: 05 dicembre 2012 — Validità/Valid: 14 dicembre 2015 – 13 settembre 2018

Si certifica che il sistema di gestione di/This is to certify that the management system of

CULLIGAN ITALIANA S.p.A.

Via Gandolfi, 6-8 -10 - 40057 Granarolo dell'Emilia (BO) - Italy

È conforme ai requisiti della norma per il Sistema di Gestione Qualità/ has been found to conform to the Quality Management System standard:

UNI EN ISO 9001:2008 (ISO 9001:2008)

Valutato secondo le prescrizioni del Regolamento Tecnico RT-05/ Evaluated according to the requirements of Technical Regulations RT-05

Questa certificazione è valida per il seguente campo applicativo:
Progettazione, produzione, commercializzazione, installazione e assistenza tecnica di impianti e apparecchiature per il trattamento delle acque
(Settore EA: 18 - 28)

This certificate is valid for the following scope:
Design, manufacture, trade, installation and maintenance of water treatment plants and equipments
(EA Sector: 18 - 28)

Luogo e Data/Place and date: Vimercate, 30 ottobre 2015

ACCREDIA

Per l'Organismo di Certificazione/ For the Certification Body

Vittore Marengoni, Management Representative

PLACE YOUR WATER TREATMENT NEEDS **IN THE HANDS OF A GLOBAL LEADER**

Culligan®

Contact your local Culligan representative for more details

Culligan reserves the right to change any technical or design specifications for the models shown in this brochure.

Place your commercial and industrial water treatment needs in the hands of a global leader.

For over 80 years, Culligan has made better water. Our global network, comprised of 900+ dealers and international licensees in over 90 countries, is dedicated to addressing your water-related problems. As a worldwide leader in water treatment, our sales representatives and service technicians are familiar with the local water conditions in your area. Being global and local position us to deliver customized solutions to commercial and industrial water issues that affect your business and your bottom line.

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