

Dr. Telis Dimitrakopoulos Vice President & Head, RephiLe Bioscience Europe Limited Aigyptou, 36 6030, Larnaca, CYPRUS

February 1st, 2016

Re: Quality Control Practices and Procedures

#### TO WHOM IT MAY CONCERN

This letter is to certify that the practices and procedures employed by RephiLe Bioscience Ltd in the manufacturing of cartridges and filtration related products are similar and of identical selection criteria as of our direct competitors, such as Millipore, Sartorius and Pall.

Please feel free to contact me directly in case of any questions or clarification.

Yours Sincerely,

Dr. Telis Dimitrakopoulos

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# CERTIFICATE OF QUALITY

RephiLe certifies that the product described below meets RephiLe product quality release criteria.

# RephiDuo LQ PAK Ultra Purification Cartridge

Catalogue Number: RR500Q101

Lot Number: Mfg Date:

This certificate describes the quality characteristics and acceptance criteria which support the high standards of quality and reliability built into RephiLe products.

## **ISO9001 Quality Standard**

The product is manufactured in a RephiLe facility whose Quality Management System is certified to the ISO9001:2008 Quality Systems Standard by an accredited registering body.

#### **Materials**

RephiDuo LQ PAK Ultra Purification Cartridges contain a combination of purification media. These purification media are carefully selected and qualified to remove contaminants from feed water.

The cartridge housing is constructed from polypropylene and polyethylene. These materials are tested suitable for the production of ultrapure water and have been qualified for low organics and ionic extractables.

### Capacity

The exclusive LeFil<sup>TM</sup> ultrapure grade mixed-bed ion-exchange resin used in this RephiDuo LQ PAK insures a minimum total capacity of 160 g NaCl. Dynamic capacity of this product is greater than 120 g NaCl.

#### Lot Release Criteria

(RephiLe Procedure RFSW Q0403.1-2009)

This manufacturing lot was statistically sampled, tested and released showing compliance with the following characteristics:

- Burst strength: Samples met the RephiLe requirements for destructive burst test at > 10 bar (> 145 psi)
- Resistivity: Samples met the requirements for ASTM Type 1 Water, achieving resistivity above 18.0 Megohm.cm at 25°C
- TOC: Samples achieved TOC levels below 10 ppb after flushing with feed water (TOC < 30 ppb).

Quality Assurance Manager

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Rev. 03/10



# CERTIFICATE OF QUALITY

RephiLe certifies that the product described below meets RephiLe product quality release criteria.

# RephiDuo L PAK Primary Purification Cartridge

Catalogue Number: RR500CP01

Lot Number: S0PDL0801 Mfg Date: 20-Dec-2010 This certificate describes the quality characteristics and acceptance criteria which support the high standards of quality and reliability built into RephiLe products.

## **ISO9001 Quality Standard**

The product is manufactured in a RephiLe facility whose Quality Management System is certified to the ISO9001:2008 Quality Systems Standard by an accredited registering body.

#### **Materials**

The RephiDuo L PAK Primary Purification Cartridge contains a combination of filtration media to remove particles, chlorine, calcium and organic contaminants from various feed water types.

The RephiDuo L PAK Primary Purification Cartridge housing is constructed from polypropylene and polyethylene which are suitable for the production of pure water and have been qualified for low organics and ionic extractables.

#### Lot Release Criteria

(RephiLe Procedure RFSW Q0403.1-2009)

This manufacturing lot was statistically sampled, tested and released showing compliance with the following characteristics:

 Burst strength: Samples met the RephiLe requirements for destructive burst test,
 > 15 bar (217 psi)

**Quality Assurance Manager** 

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# CERTIFICATE OF QUALITY

RephiLe certifies that the product described below meets RephiLe product quality release criteria.

### **Tank Filter**

Catalogue Number: **RATANKVN1** 

Lot Number: Mfg Date:

This certificate describes the quality characteristics and acceptance criteria which support the high standards of quality and reliability built into RephiLe products.

## **ISO9001 Quality Standard**

The product is manufactured in a RephiLe facility whose Quality Management System is certified to the ISO9001:2008 Quality Systems Standard by an accredited registering body.

#### **Materials**

The RATANKVN1 tank filter is equipped with a 0.2um hydrophobic filter.

The tank filters contain a combination of purification media carefully selected to remove airborne contaminants that could degrade purified water quality during storage.

The tank filters cartridges are constructed from polypropylene.

Quality Assurance Manager

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# **CERTIFICATE OF QUALITY**

This product is manufactured in a RephiLe facility in Shanghai, China. This plant's Quality Management System is certified to the ISO9001:2008 Quality Systems Standard by an accredited registering body.

RephiLe certifies that the product described below meets RephiLe product quality release criteria.

## **Liquid Level Sensor**

Catalogue Number: RAPF06805 Description: Liquid Level Sensor

For 100 Liter PE Tanks, 1/pk

Lot Number: S1PAG0101 Mfg Date: 01-July-2011

**Quality Assurance Manager** 

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# **CERTIFICATE OF QUALITY**

This product is manufactured in a RephiLe facility. This plant's Quality Management System is certified to the ISO9001:2008 Quality Systems Standard by an accredited registering body.

RephiLe certifies that the product described below meets RephiLe product quality release criteria.

#### **RO Membrane**

Catalogue Number: RAR0050HG

Description: RO Membrane w/o housing,

comparable to CDRC050HG,

1/pk

Lot Number: S4PAJ2601 Mfg Date: 11-Sep-2014

**Quality Assurance Manager** 

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