



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.

A handwritten signature in blue ink, appearing to be "Telis", enclosed in a large, hand-drawn oval.

Yours Sincerely,

Dr. Telis Dimitrakopoulos

Tel: +33 750 864 011

Email: telis.dimitrakopoulos@rephile.com

CERTIFICATE OF QUALITY

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

RephiDuo L PAK Primary Purification Cartridge

Catalogue Number: **RR500CPP1**
Lot Number: S0PDL1301
Mfg Date: 31-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 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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Rev. 12/10



CERTIFICATE OF QUALITY

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

RephiDuo L PAK Primary Purification Cartridge

Catalogue Number: **RR500CPC1**

Lot Number: S0PDL0701

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)
- Particle filtration ($d > 1\mu\text{m}$): >95%
- Chlorine removal: >99%

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 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™ 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