

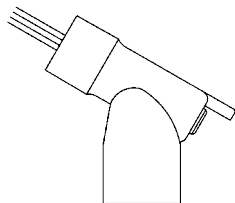
# Reusable Inspiratory Heater Wires

## Infant

**900MR754**



### Heater Wire

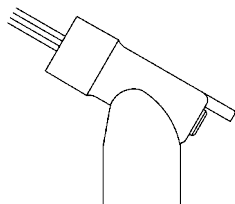


- Flows  $\geq 4\text{L/min}$
- Use with reusable inspiratory tubing approximately 1.1m (43") in length
- Compatible with MR850 & MR700 humidifiers
- Available as single item

**900MR755**

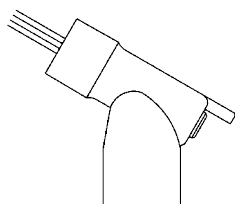


### Heater Wire



- Flows  $< 4\text{L/min}$
- Use with reusable inspiratory tubing approximately 1.1m (43") in length
- Compatible with MR850 & MR700 humidifiers
- Available as single item

**900MR524**



### Heater Wire

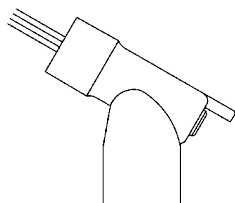
- For high frequency ventilation
- Use with reusable inspiratory tubing approximately 0.8m (30") in length
- Compatible with MR700 humidifiers
- Available as single item

## Adult

**900MR751**



### Heater Wire

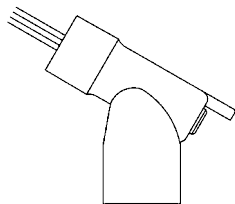


- Heater wire assembly
- Use with reusable inspiratory tubing approximately 1.5m (60") in length
- Compatible with MR850 and MR730 humidifiers
- Lemo™ connection
- Available as single item

**900MR510**



### Heater Wire



- Heater wire assembly
- Use with reusable inspiratory tubing approximately 1.3m (52") in length
- Lemo™ connection
- Compatible with MR850 & MR730 humidifiers
- Available as single item

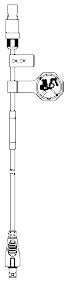
# Reusable Heater Wire Adaptors

**900MR858**



## Inspiratory Heater Wire Adaptor for reusable circuits Lemo™ style

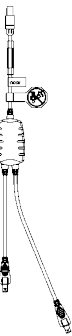
For use with the MR850 humidifier when paired with an inspiratory heated, reusable circuit



**900MR556**

## Dual Heater Wire Adaptor for reusable circuits Lemo™ style

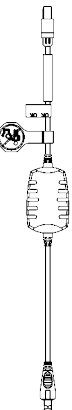
For use with the MR730 humidifier when paired with a dual heated, reusable circuit



**900MR558**

## Inspiratory Heater Wire Adaptor for reusable circuits Lemo™ style

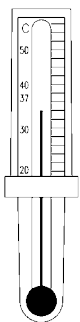
For use with the MR730 humidifier when paired with an inspiratory heated, reusable circuit



**900MR033**

## Airway Thermometer

- For measuring gas temperature when used in conjunction with the MR410 humidifier
- Available in packs of 3



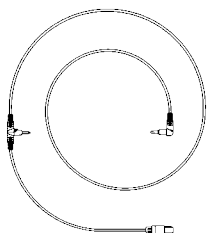
# Airway Temperature Probes

**900MR860-869**



**Temperature/Flow Probes for MR850 Humidifier**

**Right Angle Airway Probe**

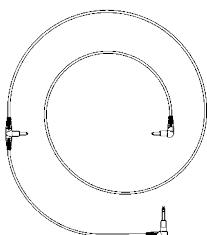


900MR863	for use with circuits 0.7m (28") in length
900MR868	for use with circuits 1.1m (44") in length
900MR860	for use with circuits 1.3m (52") in length
900MR869	for use with circuits 1.5m (60") in length
900MR861	for use with circuits 1.8m (72") in length

**900MR560-571**

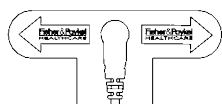
**Temperature Probes for MR700 & HC500 Series Humidifiers**

**Right Angle Airway Probe**



900MR563	for use with circuits 0.7m (28") in length
900MR568	for use with circuits 1.1m (44") in length
900MR560	for use with circuits 1.3m (52") in length
900MR569	for use with circuits 1.5m (60") in length
900MR561	for use with circuits 1.8m (72") in length
900MR571	for use with circuits 2.5m (92") in length

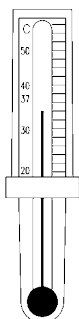
**900MR208**



**Reflective Shield  
for Temperature Probe**

- Protects airway temperature probe from radiant heat to improve humidifier performance with infant radiant warmers
- Available in packs of 20

**900MR033**



**Airway Thermometer**

- For measuring gas temperature when used in conjunction with the MR410 humidifier
- Available in packs of 3



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Zentralstelle der Länder  
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bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-244.10.08



Product Service

# EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

**No. G1 010815 0038 Rev. 01**

**Manufacturer:**

**Fisher & Paykel Healthcare Ltd.  
15 Maurice Paykel Place  
East Tamaki, Auckland 2013  
NEW ZEALAND**

**Product Category(ies):** Respiratory Gas Delivery Systems,  
Heated Humidifiers, Continuous Positive Airway  
Pressure Units, Gas Powered Pulmonary Resuscitators,  
Nasal and/or Oral Interfaces for Delivery of  
Respiratory Gases, Patient Monitoring Software for  
Use with Fisher & Paykel Healthcare Medical Devices,  
Insufflation Gas Conditioning Systems

The Certification Body of TÜV SÜD Product Service GmbH declares that the aforementioned manufacturer has implemented a quality assurance system for design, manufacture and final inspection of the respective devices / device categories in accordance with MDD Annex II. This quality assurance system conforms to the requirements of this Directive and is subject to periodical surveillance. For marketing of class III devices an additional Annex II (4) certificate is mandatory. See also notes overleaf.

**Report No.:**

**JAQ235040717**

**Valid from:**

**2019-12-12**

**Valid until:**

**2024-05-26**

**Date,**

**2019-12-12**

Christoph Dicks  
Head of Certification/Notified Body





Benannt durch/Designated by  
Zentralstelle der Länder  
für Gesundheitsschutz  
bei Arzneimitteln und  
Medizinprodukten  
www.zlg.de  
ZLG-BS-244.10.08



Product Service

## EC Certificate

Full Quality Assurance System

Directive 93/42/EEC on Medical Devices (MDD), Annex II excluding (4)  
(Devices in Class IIa, IIb or III)

**No. G1 010815 0038 Rev. 01**

**Facility(ies):**

**Fisher & Paykel Healthcare Ltd.  
15 Maurice Paykel Place, East Tamaki,  
Auckland 2013, NEW ZEALAND**

-/-



### **Zertifizierungsvertrag**

Grundlage für die Zertifikatserteilung ist die Prüf- und Zertifizierungsordnung von TÜV SÜD Product Service.

Mit Erhalt des Zertifikates erkennt der Zertifikatsinhaber die jeweils gültige Fassung der Prüf- und Zertifizierungsordnung an ([www.tuev-sued.de/ps\\_regulations](http://www.tuev-sued.de/ps_regulations)) und wird somit Partner im Zertifiziersystem von TÜV SÜD Product Service.

### **Prinzipielle Voraussetzung für die Gültigkeit des Zertifikates:**

- Gültigkeit der zitierten normativen Prüfgrundlage(n) ist gegeben und zusätzlich bei Zertifikaten mit Berechtigung zur Verwendung eines Prüfzeichens bzw. bei Zertifikaten für QM-Systeme:
- Voraussetzungen für vorschriftsmäßige Fertigung werden eingehalten.
- Die Fertigungs- bzw. Betriebsstätten werden regelmäßig überwacht.

### **Certification contract**

Certification is based on the TÜV SÜD Product Service Testing and Certification Regulations. On receipt of the certificate the certificate holder agrees to the current version of the Testing and Certification Regulations ([www.tuv-sud.com/ps\\_regulations](http://www.tuv-sud.com/ps_regulations)) and thus becomes partner in the TÜV SÜD Product Service Certification System.

### **Requirements for the validity of the certificate in principle:**

- Validity of the quoted test standard(s) In addition, for certificates with the right to use a certification mark and for QM certificates:
- Conditions for an adequate manufacturing are maintained
- Regular surveillance of the facility is performed

### **认证合约**

认证基于 TÜV SÜD 产品服务《测试及认证准则》。获得证书即表明证书持有者接受当前版本的《测试及认证准则》（见 [www.tuv-sud.com/ps\\_regulations](http://www.tuv-sud.com/ps_regulations)）并成为 TÜV SÜD 产品服务认证系统内的合作伙伴。

### **维持证书有效性的原则要求：**

- 认证所依据标准的有效性
- 此外，对于授权可使用认证标志的证书和质量管理体系证书：
- 保持充分的生产条件
  - 生产场地通过定期的监督

### **認証契約**

認証は TÜV SÜD Product Service の試験認証規約に基づく。認証書保持者は認証書を受領することにより最新の試験認証規約([www.tuv-sud.com/ps\\_regulations](http://www.tuv-sud.com/ps_regulations))に同意したものとする。その結果、TÜV SÜD Product Service 認証システムのパートナーとなる。

### **認証書の有効性に関する原則的な要求事項**

- 引用している試験規格が有効である
- さらに認証マークの使用を許諾された認証書や品質マネジメント認証書は：
- 適切な製造の条件を維持している
  - 定期的な工場監査を実施している

### **Contrato de certificação**

A certificação se baseia nos Regulamentos de Testes e Certificação do Grupo TÜV SÜD. Ao receber o certificado, o Fornecedor, titular do certificado concorda com a versão atual dos Regulamentos de Testes e Certificação do Grupo TÜV SÜD ([www.tuv-sud.com/ps\\_regulations](http://www.tuv-sud.com/ps_regulations)) e assim, torna-se parceiro no Sistema de Certificação de Produtos e Serviços TÜV SÜD.

### **Requisitos para a validade do certificado (em princípio):**

- Validade da(s) norma(s) de ensaio(s) referenciada(s).
- Adicionalmente, para os certificados com o direito ao uso da marca de certificação e para certificados de SG:
- Condições de fabricação adequada estão mantidas.
  - Auditoria de monitoração realizada regularmente.



# Certificate

No. Q5 010815 0037 Rev. 01

**Holder of Certificate:** Fisher & Paykel Healthcare Ltd.  
15 Maurice Paykel Place  
East Tamaki, Auckland 2013  
NEW ZEALAND

**Facility(ies):** Fisher & Paykel Healthcare Ltd.  
15 Maurice Paykel Place, East Tamaki,  
Auckland 2013, NEW ZEALAND

See scope of certificate

**Certification Mark:**



**Scope of Certificate:** Design and Development, Production and Distribution of Respiratory Gas Delivery Systems, Heated Humidifiers, Infant Radiant Warmers, Continuous Positive Airway Pressure Units, CPAP Data Transmission Equipment, Gas Powered Pulmonary Resuscitators, Nasal and/or Oral Interfaces for Delivery of Respiratory Gases, Patient Monitoring Software for Use with Fisher & Paykel Healthcare Medical Devices, Insufflation Gas Conditioning Systems

**Applied Standard(s):** EN ISO 13485:2016  
Medical devices - Quality management systems - Requirements for regulatory purposes (ISO 13485:2016)  
DIN EN ISO 13485:2016

The Certification Body of TÜV SÜD Product Service GmbH certifies that the company mentioned above has established and is maintaining a quality management system, which meets the requirements of the listed standard(s). All applicable requirements of the testing and certification regulation of TÜV SÜD Group have to be complied with. For details and certificate validity see: [www.tuvsud.com/ps-cert?q=cert:Q5 010815 0037 Rev. 01](http://www.tuvsud.com/ps-cert?q=cert:Q5 010815 0037 Rev. 01)

# Certificate

No. Q5 010815 0037 Rev. 01

Report No.: JA1669262  
Valid from: 2021-11-14  
Valid until: 2024-11-13

Date, 2021-11-11



Christoph Dicks  
Head of Certification/Notified Body