

## EC Certificate

DGM-727

This is to certify that the quality system of

### SP Medical A/S

Møllevej 1  
4653 Karise  
Denmark

has been approved in conformity with the requirements of

#### **Annex II, section 3.2 - Full quality assurance system**

of Council Directive 93/42/EEC concerning medical devices as amended and transposed into Danish law.

The scope of the certification is:

**Design, manufacture and final inspection of sterile PTFE coated Guide Wires, sterile hydrophilic coated Guide Wires and sterile stainless steel Guide Wires, in class IIa as well as PTCA Guide Wires in class III**

The EC certificate is valid provided that the quality system continues to conform to the above-mentioned scope and provided that the company does not introduce substantial changes to the quality system without the approval of DS Certificering A/S. This EC certificate is issued pursuant to the DS Certificering A/S rules for the certification of medical devices and entitles the certificate holder to affix the CE mark.



**Benedikte Blom**  
Authorized person

Valid from: 2011-05-16  
Valid until: 2012-11-26  
Initial date of issue: 2011-05-11  
Reference: Aur2a1104v10f766

#### **DS Certificering A/S**

*Notified Body, Identification No. 0543*  
Kollegievej 6, DK-2920 Charlottenlund, Denmark

The following product families in class III are covered by the certificate and by EC Design Examination Certificate DGM-729:

### **Champion PTCA Guide Wires**

The following product families in class IIa are covered by the certificate:

### **Seldinger and PTC Guide Wires Hydrophilic Guide Wires**

With the following site(s):

**SP Medical Sp.z.o.o  
UI Ceramiczna 2  
98-220, Zdunska Wola  
Poland**

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