



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 transposed into Danish law excluding Annex II, section 4.

The certificate covers the following activities:

**Design, manufacture and final inspection of sterile hydrophilic,  
PTCA, and PTFE coated Guide Wires and stainless steel Guide Wires  
in class IIa and 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 Presafe Denmark A/S. This EC certificate is issued pursuant to the Presafe Denmark A/S' terms and conditions for the certification of medical devices and entitles the manufacturer to affix the CE mark. The certificate is based on successful audit of the manufacturer. The manufacturer is subject to periodical audits as per the Directive.

  
Heidi Jørgensen  
Authorized person

For Presafe Denmark A/S

Date of issue: 2017-09-14  
Expires: 2022-09-14  
Initial date of issue: 2011-05-11  
Reference: aur2a1708v220f766

The following product families in class IIa are covered by the certificate:  
**Accoat™ Standard Guide Wires**

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 III are covered by the certificate and by EC Design Examination Certificate DGM-780:  
**Accoat Guide Wires**

The following product families in class III are covered by the certificate and by EC Design Examination Certificate DGM-786:  
**Poseidon Hydrophilic Nitinol Guide Wires**

With the following site(s):  
**SP Medical Sp.z.o.o**  
**Ul. Ceramiczna 2**  
**98-220, Zdunska Wola**  
**Poland**

Certificate number: DGM – 727  
Certificate type: EC Certificate

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