

Quality System Certificate

DGM-728

This is to certify that the quality system of

SP Medical A/S

**Møllevej 1
4653 Karise
Denmark**

fulfils the requirements in

DS/EN ISO 13485:2003 & DS/EN ISO 9001:2008

The scope of the certificate is:

Development and manufacture of Guide Wires. Construction, production, assembly and decoration of injection moulded plastic parts.

The 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. Certifications to DS/EN ISO 13485:2003, EN ISO 13485:2003, ISO 13485:2003, DS/EN ISO 9001: 2008, EN ISO 9001:2008 and ISO 9001:2008 include the requirements of the valid corrigenda. The quality system certificate is issued pursuant to the DS Certificering A/S rules for the certification of quality systems for medical devices.


Carsten Worm Jensen
Authorized person

Valid from: 2011-05-11
Valid until: 2013-02-28
Initial date of issue: 2011-05-11
Reference: Aur1104v10f766

DS Certificering A/S

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

Additional site covered by the certificate:

SP Medical Sp. z.o.o
Ul. Ceramiczna 2
98-220 Zduńska Wola
Poland

Certificate number: DGM-728
Certificate type: Quality System
Certificate

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