

Salalah Medical Device Manufacturing Corporation

Plot No. 8 - Raysut Industrial Area, Salalah,
Post Code 211, Sultanate of Oman

Device Identification:
Vascular Access and Interventional Guidewires.

Intended Purpose of Device:
To allow percutaneous access to the central circulatory vasculature using the Seldinger technique to facilitate the subsequent introduction of an intravascular device.

has been assessed and certified as meeting the requirements of

Directive 93/42/EEC on Medical Devices Annex II, section 4

It is certified that the manufacturer's design dossier (and product, where applicable) for the above device has been examined and, based on the evidence submitted, it is considered that the device conforms to the relevant Essential Requirements of EC Directive 93/42/EEC.

This certificate is issued in conjunction with a certificate covering the full quality assurance system to Annex II, which must be subject to satisfactory surveillance audits.

This certificate is valid from 20 April 2011 until 20 April 2016
Issue 1

Certification is based on report number(s) GB/PC DDE 224989 dated 04 April 2011

Addenda to that report have been issued on the following dates:

<u>Addendum Date</u>	<u>Reason for Addendum</u>
N/A	N/A

Authorised by

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