

Finesse Medical Limited

Unit 4, Royal Canal Business Park, Athlone Road, Longford, Ireland

Device Identification:

**Zonex® sterile silver alginate antimicrobial catheter dressing,
Zonis® sterile silver alginate antimicrobial catheter dressing.**

Medical Purpose of Device:

**Indicated for the management of wounds caused by the use of
vascular and non-vascular percutaneous medical devices
(e.g. catheters, chest and feeding tubes and external fixator pins).
For external use only and may be used in the management of infected
wounds under medical supervision at the discretion of the physician.**

Has been assessed and certified as meeting the requirements of

EC 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 regular compliance visits.

This certificate is valid from 01 June 2009 until 22 July 2013
Issue 2

Certification is based on report number(s) PC DDE 219218 dated 04 July 2008

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

Addendum Date
29 May 2009

Reason for Addendum
To include new brand name Zonis.

Notified Body Number 0120

Authorised by

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