



Products Certification Body
Institute for Testing and Certification, Inc.
Zlin, Czech Republic – www.itczlin.cz

CERTIFICATE

No. 10 0933 V/ITC

confirms that the products – medical device of the Class I according to the Council Directive 93/42/EEC, model

ORLocate™ System (exclude the tagged sponges)

manufactured by company

Haldor Advanced Technologies Ltd.

2 Habanai st. Hod Hasharon, 45319 Israel

complies with the applicable essential requirements of the Directive 93/42/EEC.

Referring to the intended use, the ITC Products Certification Body has conducted with successful results the product-examination of the certified product according to the relevant parts of the above mentioned Directive and appropriate harmonized European standards.

Based on audit of the quality management system implemented by the manufacturer, the ITC Products Certification Body confirms a manufacturer's ability to keep permanently the requested safety and quality level.

The more detailed product description, documents, assessment procedures and evaluations of the examination and of the management system audit are presented in the Final Report No. 313600234/2010, which is enclosed to this certificate.

This Certificate is issued under the following conditions:

1. *It applies only to the above referenced models of the medical devices.*
2. *The manufacturer is obligated to assure that all medical devices of the respective models conform to the type approved by this Certificate.*
3. *The Certificate remains valid until the manufacturing conditions, the quality system or relevant legislation are changed but until the **15th November 2015** at the latest.*
4. *The validity is conditioned by positive results of periodic surveillance audits.*
5. *After fulfilling of the relevant EU legislation requirements, the manufacturer shall affix to each medical device, of the above referenced models, the CE-marking according to this example:*

CE

Issued in Zlin, on 16th November 2010



RNDr. Radomír Čevelík
General Director.