



National Standards Authority of Ireland

IRISH STANDARD

I.S. EN 1441:1998

ICS 11.040.01

MEDICAL DEVICES - RISK ANALYSIS

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*This Irish Standard was
published under the
authority of the National
Standards Authority of
Ireland
and comes into effect on
April 17, 1998*

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DECLARATION
OF
SPECIFICATION
ENTITLED

MEDICAL DEVICES - RISK ANALYSIS

AS

THE IRISH STANDARD SPECIFICATION FOR

MEDICAL DEVICES - RISK ANALYSIS

NSAI in exercise of the power conferred by section 16 (3) of the National Standards Authority of Ireland Act, 1966 (No. 28 of 1996) and with the consent of the Minister for Enterprise, Trade and Employment, hereby declares as follows:

1. This instrument may be cited as the Standard Specification (Medical devices - Risk analysis) Declaration, 1998.
2. (1) The Specification set forth in the schedule to this declaration is hereby declared to be the standard specification for Medical devices - Risk analysis. The Schedule comprises the text of EN 1441:1997.
(2) The said standard specification may be cited as Irish Standard EN 1441:1998 or as I.S. EN 1441:1998.

EUROPEAN STANDARD
NORME EUROPÉENNE
EUROPÄISCHE NORM

EN 1441

October 1997

ICS 11.040.01

Descriptors: medical equipment, safety, accident prevention, hazards, statistical analysis, estimation, acceptability, specifications, information

English version

Medical devices - Risk analysis

Dispositifs médicaux - Analyse des risques

Medizinprodukte - Risikoanalyse

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