



National Standards Authority of Ireland

IRISH STANDARD

I.S. EN 1441:1998

ICS 11.040.01

## MEDICAL DEVICES - RISK ANALYSIS

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**DECLARATION**  
**OF**  
**SPECIFICATION**  
**ENTITLED**  
**MEDICAL DEVICES - RISK ANALYSIS**

**AS**  
**THE IRISH STANDARD SPECIFICATION FOR**  
**MEDICAL DEVICES - RISK ANALYSIS**

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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

**EN 1441**

NORME EUROPÉENNE

EUROPÄISCHE NORM

October 1997

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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

This European Standard was approved by CEN on 13 September 1997.

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EUROPAISCHES KOMITEE FÜR NORMUNG

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