

**EUROPEAN COMMISSION**  
**DG ENTERPRISE**  
**Directorate G**  
**Unit 4 - Pressure Equipment, Medical Devices, Metrology**

## MEDICAL DEVICES : Guidance document

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**MEDDEV 2.5/5 Rev. 3**

**February 1998**

GUIDELINES RELATING TO THE APPLICATION OF:  
THE COUNCIL DIRECTIVE 90/385/EEC ON ACTIVE IMPLANTABLE MEDICAL DEVICES  
THE COUNCIL DIRECTIVE 93/42/EEC ON MEDICAL DEVICES

**" TRANSLATION PROCEDURE "**

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## **Translation procedures**

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As part of the quality system or of the documents defining the manufacturing process, the manufacturer should have procedures for ensuring accurate translation of e.g. labelling, instructions for use and product claims in marketing material.

These are especially important for user instructions where the safety and claimed performance of the device may be compromised through inadequate translation.

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