

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

MEDICAL DEVICES : Guidance document

MEDDEV 2.5/5 Rev. 3
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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

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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