

## **MEDICAL DEVICES : Guidance document**

---

|                            |
|----------------------------|
| <b>MEDDEV 2.5/5 Rev. 3</b> |
| <b>February 1998</b>       |

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 "**

---

---(0)---

## 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.

---( )---



医课汇  
公众号  
专业医疗器械资讯平台  
WECHAT OF  
HLONGMED



hlongmed.com  
医疗器械咨询服务  
MEDICAL DEVICE  
CONSULTING  
SERVICES



医课培训平台  
医疗器械任职培训  
WEB TRAINING  
CENTER



医械宝  
医疗器械知识平台  
KNOWLEDG  
ECENTEROF  
MEDICAL DEVICE



MDCPP.COM  
医械云专业平台  
KNOWLEDG  
ECENTEROF MEDICAL  
DEVICE