

## Links to websites

### Europe

Links to standards harmonized under European medical device legislation:

Under Council Directive 93/42/EEC of 14 June 1993 concerning medical devices:

<http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/reflist/meddevic.html>

Under Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices:

<http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/reflist/invimedd.html>

Under Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices:

<http://europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/reflist/implmedd.html>

### Canada

Link to the Policy on Recognition and Use of Standards under the Medical Devices Regulations for Health Canada:

[http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/pol/standards\\_normes\\_pol\\_e.html](http://www.hc-sc.gc.ca/dhp-mps/md-im/applic-demande/pol/standards_normes_pol_e.html)

### US

Link to FDA standards program:

<http://www.fda.gov/cdrh/stdsprog.html>

### Australia:

<http://www.tga.gov.au/docs/html/devstdord.htm>

### Japan:

Assessment standards:

[http://www.whoarei.mhlw.go.jp/cgi-bin/t\\_docframe.cgi?MODE=hourei&DMODE=CONTENTS&SMODE=NORMAL&KEYWORD=&EFSNO=547](http://www.whoarei.mhlw.go.jp/cgi-bin/t_docframe.cgi?MODE=hourei&DMODE=CONTENTS&SMODE=NORMAL&KEYWORD=&EFSNO=547)

1 approval standard; [http://www.piis.pref.mie.jp/dat/pdf/10002245\\_001.pdf](http://www.piis.pref.mie.jp/dat/pdf/10002245_001.pdf)

1 approval standard; [http://www.piis.pref.mie.jp/dat/pdf/10002246\\_001.pdf](http://www.piis.pref.mie.jp/dat/pdf/10002246_001.pdf)

1 approval standard; [http://www.piis.pref.mie.jp/dat/pdf/10002247\\_001.pdf](http://www.piis.pref.mie.jp/dat/pdf/10002247_001.pdf)

1 approval standard; [http://www.piis.pref.mie.jp/dat/pdf/10002248\\_001.pdf](http://www.piis.pref.mie.jp/dat/pdf/10002248_001.pdf)

1 approval standard; [http://www.piis.pref.mie.jp/dat/pdf/10002249\\_001.pdf](http://www.piis.pref.mie.jp/dat/pdf/10002249_001.pdf)

1 approval standard; [http://www.piis.pref.mie.jp/dat/pdf/10002250\\_001.pdf](http://www.piis.pref.mie.jp/dat/pdf/10002250_001.pdf)

1 approval standard; [http://www.piis.pref.mie.jp/dat/pdf/10002251\\_001.pdf](http://www.piis.pref.mie.jp/dat/pdf/10002251_001.pdf)

1 approval standard; [http://www.piis.pref.mie.jp/dat/pdf/10002252\\_001.pdf](http://www.piis.pref.mie.jp/dat/pdf/10002252_001.pdf)

1 approval standard; [http://www.piis.pref.mie.jp/dat/pdf/10002253\\_001.pdf](http://www.piis.pref.mie.jp/dat/pdf/10002253_001.pdf)

1 approval standard; [http://www.piis.pref.mie.jp/dat/pdf/10002254\\_001.pdf](http://www.piis.pref.mie.jp/dat/pdf/10002254_001.pdf)

1 approval standard; [http://www.piis.pref.mie.jp/dat/pdf/10002480\\_001.pdf](http://www.piis.pref.mie.jp/dat/pdf/10002480_001.pdf)