Underwriters Laboratories Inc.®

UL Medical Device Programs

Your Premier Single-channel Source for Global Compliance

Working for
a safer world

Get your medical devices approved for world markets

Multiple Certifications in One Process

UL assesses and certifies to all recognized and harmonized medical standards - CE Marking (Europe); UL Mark and FDA (Food and Drug Administration) 510k clearance (USA); CB report, EMC testing and management system registration (international) - enabling us to offer a single hassle-free solution for multiple market access.

Our Medical Experts Understand Your Needs

UL's engineers, technical experts, and assessors can be relied on to help you achieve global compliance. UL participated in drafting the third edition of IEC 60601-1, and is also a Notified Body for CE certifications.

Efficient and Flexible Certification Processes

To stay ahead of the competition, you need streamlined services with flexible options. UL's interactive testing programs, field evaluations, research testing and witness testing can all be customized to meet your production schedule and planned time to market.

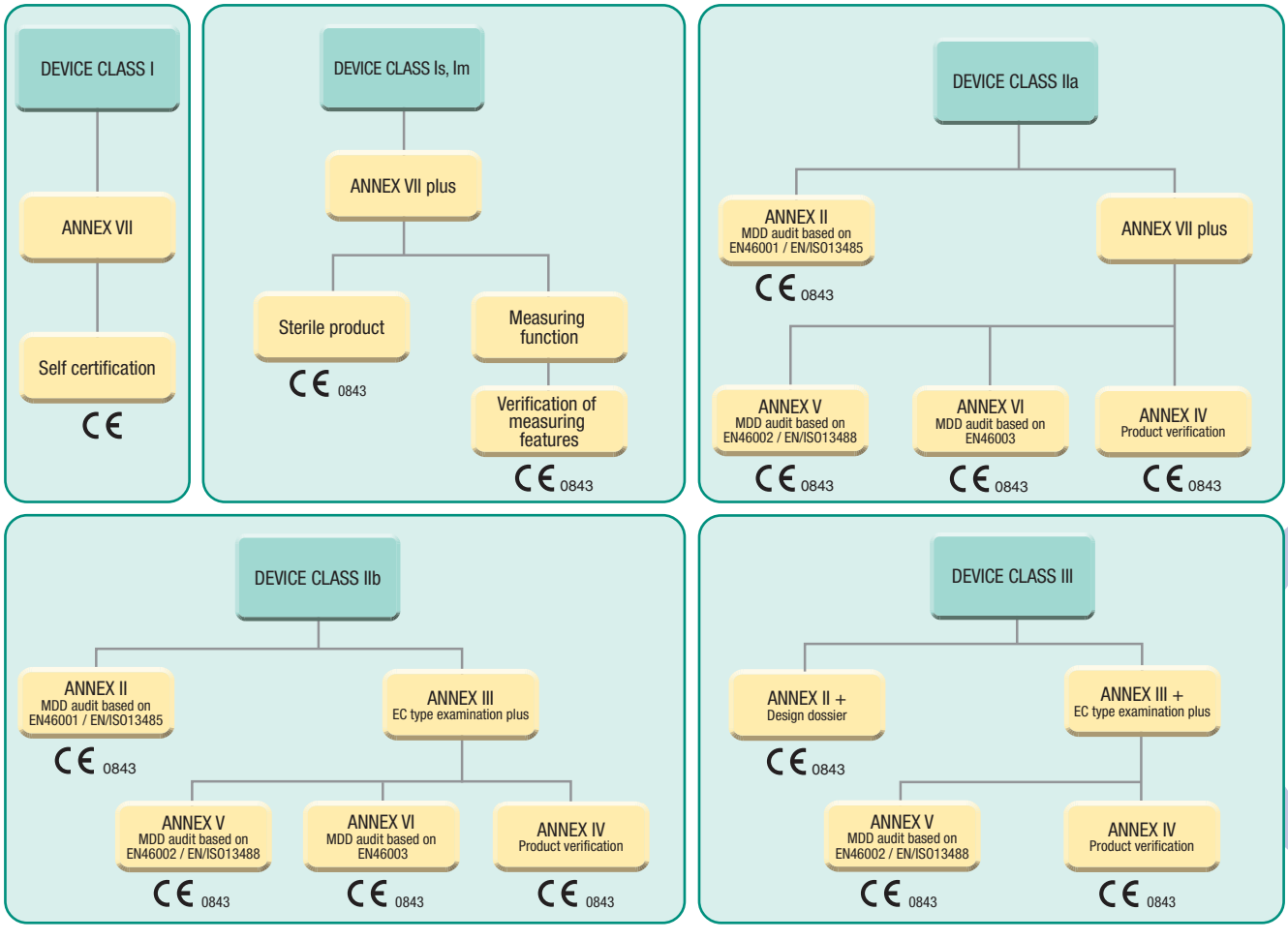
Value-Added Assessment

UL's assessment process includes not just routine procedures, but also expert observations and debriefing that help ensure continued improvement and compliance. Our technical and customer service professionals are strategically located worldwide to provide you with up-to-date regulatory requirements, market information, on-site training and technical support.

Medical Devices Directive (MDD)

It is mandatory for medical devices marketed and sold in Europe to comply with the Medical Devices Directive 93/42/EEC (MDD). Depending on the risk classification of the product, compliance can be self-declared by the manufacturer or assessed by a Notified Body such as UL (CE 0843).

Optional conformity assessment routes and subsequent level of Notified Body involvement



Regulatory Services

- CE Marking (MDD, IVDD) CE 0843
- U.S. FDA Pre-market Notification (510(k)) Third Party Review
- CMDCAS Registration for Canada

Product Safety Testing & Certification

- Testing to IEC 60601-1, IEC 60601-1-xx, UL 60601-1, C22.2No.601-1-M90, UL 1431, etc. . .
  - UL Mark
  - C-UL Mark
  - UL Demko Mark
  - Medical CB Test Report
- EMC Testing (IEC 60601-1-2)
- Software Certification (IEC 60601-1-4)
- JIS Testing and Evaluation for Japan

Management System Registration

Accredited by RAB, SCC, RvA and UKAS

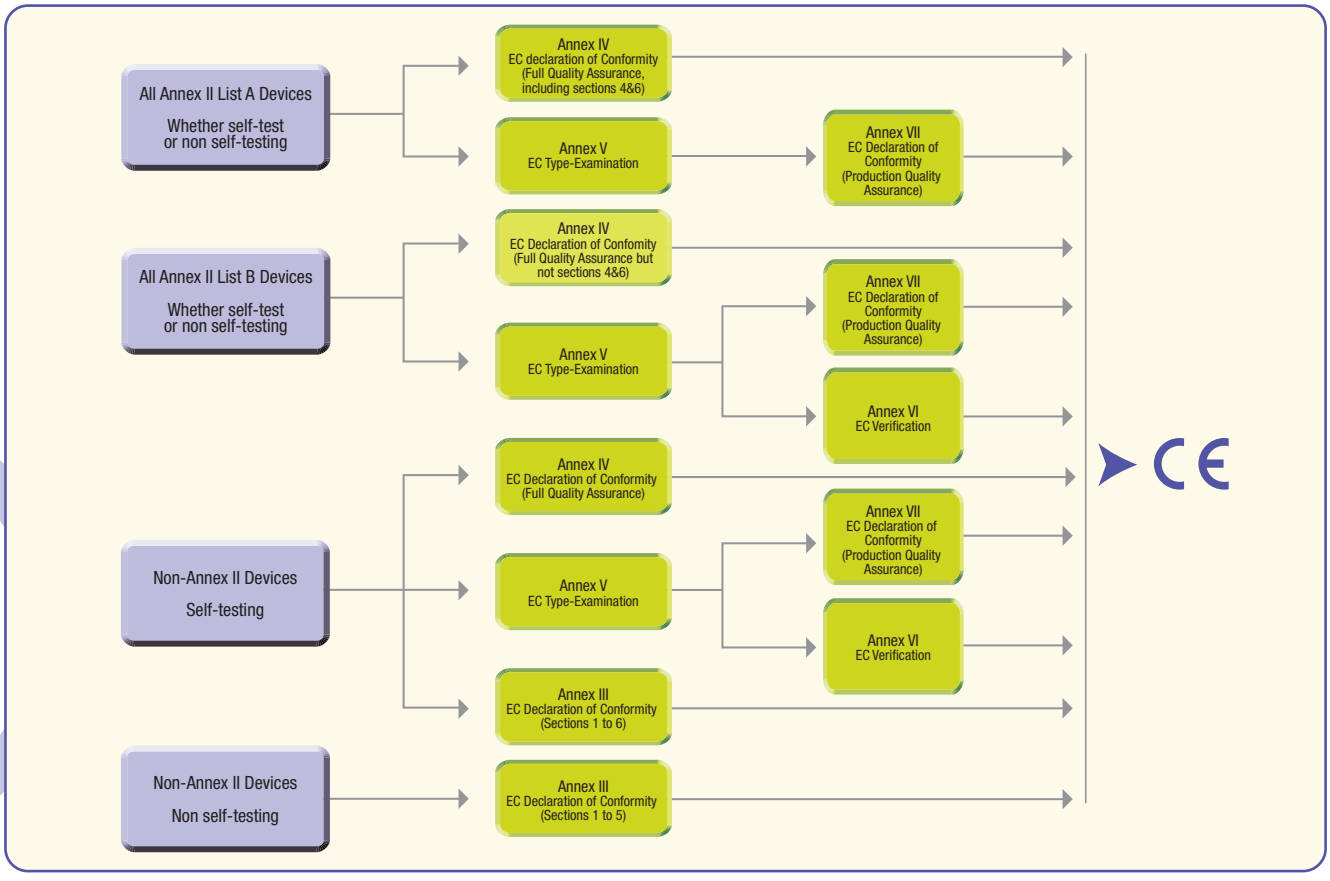
- EN/ISO 13485
- EN 46001
- ISO 9001

In-Vitro Diagnostic Directive (IVDD)

Europe's In-Vitro Diagnostic Directive 98/79/EC (IVDD) requires manufacturers to affix the CE Marking on their products from late 2003. Products needing Notified Body involvement include those used in blood or tissue donations, blood sugar monitoring, diagnosis of certain infectious diseases (particularly of the unborn), self-test devices, PKU, PSA and trisomy 21.

UL is one of the first Notified Bodies to be appointed under the IVDD. UL also offers management system certification to ISO 9001, EN 46001/2 and ISO 13485/8, as well as a technical file review service for those self-declaring conformity for low-risk devices.

Conformity assessment routes for CE marking under IVDD



Benefit from UL's Programs for medical devices now to enjoy:

- **UL's integrity:** enhance your competitive position by selecting a highly reputable service provider
- **End-to-end solutions:** use UL's full spectrum of medical device certifications through only one single channel
- **UL's expertise:** professional advice on compliance requirements
- **Streamlines certification process:** choose the service option that fits your schedule. Avoid duplicate testing and delays in order to speed up your path to successful certification and reduce your costs
- **Additional value:** supplementary benefits and services to satisfy your business needs

UL Contacts in Asia

	Tel	Fax	Email
Beijing	+86-10-6787-6044	+86-10-6787-4606	ul.bj.cn@cn.ul.com
Guangzhou	+86-20-8348-6999	+86-20-8348-6777	ul.gz.cn@cn.ul.com
Hong Kong	+852-2276-9000	+852-2276-9828	ul.hk@hk.ul.com
India	+91-80-558-1773-76	+91-80-558-1771	ul.in@in.ul.com
Japan	+81-596-24-6717	+81-596-24-8020	ul.jp@jp.ul.com
Korea	+822-2009-9000	+822-2009-9400	ul.kr@kr.ul.com
Malaysia	+603-5632-5922	+603-5632-5923	ul.my@my.ul.com
Shanghai	+86-21-6288-2990	+86-21-6288-2980	ul.sh.cn@cn.ul.com
Singapore	+65-6274-0702	+65-6271-3867	ul.sg@sg.ul.com
Suzhou	+86-512-6808-6400	+86-512-6808-4099	ul.sz.cn@cn.ul.com
Taiwan	+886-2-2896-7790	+886-2-2891-7644	ul.tw@tw.ul.com

www.UL-asia.com