PRODUCT TESTING (LASER & LED)

Test & Certification of Laser & LED Products to European, USA & International Standards

UKAS Accredited* Laser & LED Testing

Test Lab 2682

Lasermet is the UK's leading test house for testing to the following standards:

- *BS/EN 60825-1 / IEC 60825-1**
- *BS/EN 60825-2 / IEC 60825-2*
- *BS/EN 60825-12 / IEC 60825-12**
- *BS/EN 60601-2-22 / IEC 60601-2-22**
- *21 CFR 1040.10*
- *BS/EN 60825-1:2014, 2007, 2001 (off-site)*

and is the only test house with UKAS accreditation for laser testing to BS EN IEC 60825 and LED testing.

*As from 1st July 2020, Lasermet is UKAS Accredited to carry out **laser safety testing offsite** to the following standard:-*
BS EN 60825-1:2014, 2007, 2001 (off-site)

This enables customer to have their laser system tested in situ at their location. This is highly advantages as it means Lasermet can provide UKAS Accredited laser safety testing on large laser systems which are impractical to move.

Photochemical Hazard Laser Output Safety Testing

WHICH STANDARD DO I USE TO TEST LEDS OR LASERS?

More information on these standards can be found below:

THESE ARE THE EUROPEAN, INTERNATIONAL AND USA LASER SAFETY STANDARDS:

- *Prototype & Finished Product Testing*
- *Consultancy at the Design Stage*
- *CE Marking, Laser Safety Standards & FDA (CDRH) Registration*
- *Important – Single Fault Failure Requirements*
- *Equipment Required for Testing*
- *Advice note – Single Fault Protection*

Prototype & Finished Product Testing

We will test and certify your prototype or completed product to the appropriate standard or standards and provide a full test report including details of:

- *Measurement test results*
- *Accessible Emission Limits*
- *Required Engineering Controls*

DOWNLOADS

- *UKAS Certificate 2019*
- *FDA Laser Notice 50*
- *Advice note v2*

To find out more about Product Testing (Laser & LED), contact us now!

Call us now: 01202 770740

Email: office@lasermet.com

Or use our contact form:

CONTACT US

SEE ALSO:

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Test & Certification of Laser & LED Products to European, USA & International Standards

- *Required Engineering Controls*
- *Required Labelling*
- *Required information in User Manual and Product Brochures*
- *Failure modes of drive electronics and other reasonably foreseeable failures affecting safety*

Where a product fails to meet the desired classification due to minor failures, we will issue a classification conditional upon making listed changes (eg labelling, user information and minor engineering changes). Where a retest is required this will normally be carried out at a reduced fee.

Consultancy at the Design Stage

Imagine this scenario:

You spend two years developing a laser product. Understandably, your focus is on achieving a high performance product at a price which will sell. ***Laser safety*** *testing is well down the list of priorities. So only when you are nearing production do you submit your product for* ***laser safety*** *testing – only to find that changes are required in order to meet the desired laser classification. At a late stage even small changes can be costly, and will delay production and sales. Significant design changes can cost a huge amount of time and money.*

To avoid this scenario we recommend that you get us involved at an early stage in the design process to advise you on the desirable class of your product and ensure that it is designed to meet the requirements of that class. We also particularly draw your attention to the Single Fault Failure requirements discussed below.

CE Marking, Laser Safety Standards and FDA (CDRH) Registration

EUROPE

As part of the process of CE marking, all laser and LED products sold in Europe must be certified to EN 60825-1* (EN 60825-2 for fibre optic laser communication products, EN 60825-12 for open beam laser communication products). Please note that the same requirements apply for LED products as for laser products. In the following notes read 'laser & LED' for 'laser'. EN 60825-1 is called up by the all of the following directives:

- *Low Voltage Directive*
- *Machinery Directive*
- *General Product Safety Directive*
- *Radio & Telecommunication Transmission Equipment Directive*
- *Medical Devices Directive*

and thus applies to all laser products*. Manufacturers can self certify their equipment to EN 60825-1, but the standard is highly complex and difficult to interpret and in many cases an expert is required to obtain the correct laser Class for the product. In any case many manufacturers prefer to have independent verification of their compliance with the classification requirements.

In Europe, product conformity is achieved by requiring manufacturers to certify to the applicable standards for their product. The onus is on the manufacturer to identify the relevant standards, design the product accordingly, and make a declaration of conformity in the user instructions. It is then the responsibility of the various national enforcement bodies (eg. The Trading Standards Organisation in the UK) to detect non-conformances and intervene where necessary. The standards are set by committees of experts and are under under continual review and enhancement. This system places considerable responsibility and trust in the hands of the manufacturers, but allows standards to be kept up to date with changing technology, knowledge and current practice.

USA

The situation in the USA is somewhat different, at least as far as laser products are concerned. Product **safety** in the USA is controlled by Federal Regulations which are enforced by the Food & Drug Administration (FDA), and in the case of laser products by a division of the FDA known as the Center for Devices and Radiological Health (CDRH). The Federal Regulations are written into law and manufacturers are legally obliged to comply with them. They are also legally obliged to register the products with the FDA prior to selling or importing them into the country. More information about FDA registration can be found here.

The regulation controlling laser products is known as 21 CFR 1040.10. This regulation was written into law in the 1970s and has been unchanged ever since. Consequently it is now very out of date. Nevertheless it still applies and until recently all laser products sold in the USA had to conform to this regulation. However, in 2001 the CDRH issued 'Laser Notice 50' which states that the FDA will now accept IEC classification and labelling. So now manufacturers selling their products in the USA have the choice of using classification and labelling to IEC 60825-1 or 21 CFR 1040.10. In both cases the products must be registered with the FDA. Note that LED products are not covered by 21 CFR 1040.10 (or any other Federal Regulation) and do not need to be registered.

Please note that, although the CDRH laser regulations are Federal Law, registration is a 'self declare' process as with EU regulations. However, CDRH do sometimes check submissions and if they do not meet the Federal Regulations may ban use of the offending products or may demand that all equipment in place be changed to meet the regulations. Note also that FDA **never** 'approve' equipment, though on rare occasions they may indicate that they have reviewed the submission and have no further questions regarding the submission.

INTERNATIONAL

IEC 60825-1, IEC 60825-2 and IEC 60825-12 are currently identical to the corresponding EN standards discussed above (although the EU standards agencies reserve the right to vary from them if considered necessary for safety reasons). These standards are applicable in Japan, Australia, Canada and pretty much every other country not already

reasons). These standards are applicable in Japan, Australia, Canada and pretty much every other country not already covered. Since IEC 60825-1 is also applicable in Europe (under the EN designation) and the USA (with the exception of some clauses), it is now very much the worldwide laser safety standard.

* Unless the products are inherently Class 1. 'Inherently Class 1' means that the product does not contain an embedded laser and cannot exceed Class 1 under any circumstances.

Important – Single Fault Failure Requirements

EN and IEC 60825-1 and -12 require classification to be carried out at the highest emitted power under reasonably foreseeable single fault failure conditions (EN / IEC 60825-2 uses 'reasonably foreseeable failure conditions'). Most notably this affects electronic drive circuits for diode lasers, where a component failure, such as a transistor going short circuit, may drive up the output power of the laser and cause the product to emit above the AEL of the desired Class. **In such a case the product must be classified at the higher class** unless the electronics is redesigned to eliminate the problem. Many manufacturers overlooked this requirement in the past and succeeded in complying because the diodes were generally low power and would often be destroyed very quickly when subjected to a higher drive current than that intended by the circuit design. However, with the increase in power and reduction in cost of **laser** diodes most manufacturers are using higher power diodes operating at a small percentage of their maximum output, to increase reliability. The result is that in the case of a component failure increasing the drive current of the **laser** diode, many of these devices will run quite happily at twenty times the intended product output. This may not only present a classification problem but in some cases a serious **safety** issue.

Equipment Required for Testing Laser & LED Products

1. *1 off Working equipment*
2. *2 off Laser diodes and (if applicable) laser modules*
3. *1 off Circuit diagram for laser drive circuit and module (if applicable).*
4. *1 off Set of printed circuit masks and drawings showing component layout.*
5. *1 off Explanation of circuit function (particularly if the circuitry is complex).*
6. *1 off Manufacturers specification sheet for laser diode and any integrated circuits directly associated with the laser*
7. *1 off Any relevant instruction manuals*
8. *1 off Interlock® circuit (if applicable)*
9. *1 off Circuit diagram for Interlock® (if applicable)*

For LED products read 'LED' instead of 'Laser'. Also please supply 5 off spare LEDs for number 2).

NB: *If some of the information/items requested above is/are not supplied it may take considerable time to analyse the circuit which may result in extra test costs being charged. In some cases it may be impossible to classify the equipment without all the applicable samples/information listed above.*

Consequently we strongly advise manufacturers to consider their drive electronics very carefully to ensure that the reasonably foreseeable single fault failure requirement has been covered. Otherwise serious problems are likely to arise at the testing stage, which is usually when manufacturers are under pressure to get the product on sale. A Lasermet advice note is available for download, ***see Advice note v2*** at the top of this page, giving outline guidance on protection against single fault conditions.

Lasermet Limited
Lasermet House
137 Hankinson Road
Bournemouth,
Dorset
BH9 1HR, UK

Registered in England: No. 02084778
VAT No. GB 522 0236 02

Since 1987, Lasermet have advised British and European industry on **laser safety** (including British Aerospace, Hewlett Packard, BBC, DTI, BSI, Shorts, Fisons, Carlton TV), and carried out UK and EU funded research projects into the field (EU 194, EU 642, EU 643). Since 1996 we have been manufacturing and distributing a full range of **high quality laser safety products**.