

# Laser and Light Intervention Standards

Dr Elizabeth Raymond Brown and clinical technologist Dr Godfrey Town present the different standards and regulations in the UK for laser and light interventions

**Lasers and intense light sources (ILS) – which include intense pulsed light (IPL) and light emitting diode (LED) technologies – are suitable for a range of interventions, from invasive surgical procedures, such as laser lipolysis and ablative skin rejuvenation, to non-invasive therapies, such as hair reduction, tattoo removal and non-ablative skin rejuvenation.** Lasers and ILS are subject to standards and regulatory controls because of the unique potential hazard they pose to tissues of the eye and skin, including the risk of blindness and skin burns.<sup>1,2</sup> In the European Union (EU), including the UK, devices based upon optical energy have been used for both medical and cosmetic applications. The Care Quality Commission (CQC) defines the scope of medical or surgical procedures as treatments provided by a healthcare professional, which are related to disease, disorder or injury.<sup>3</sup> This is reflected in the European Medical Device Regulation (MDR),<sup>4</sup> which comprises requirements that relate to the safety and performance of medical devices. This article describes the different standards and regulations for medical and cosmetic devices in the UK and explains what aesthetic practitioners need to know with regard to purchasing and training.

## EU regulation of device manufacturing

Any medical device placed on the EU market must comply with relevant legislation. Manufacturers' products which meet 'harmonised standards' have a presumption of conformity to the MDR (previously the Medical Device Directive or MDD). These products must have a Conformité Européenne (CE) mark applied. To ensure a device meets the MDR's requirements, a device manufacturer may nominate an organisation called a Test House or Notified Body which has been recognised by an EU Member Government. This Notified Body may be a private sector organisation or a government agency, and serves as an independent testing service. It will undertake equipment tests against the relevant European Standards, called European Norms (EN), and scrutinise user guides, labelling equipment features and functions.<sup>5</sup> For example, a key standard for medical lasers is EN 60601-2-22:2013 'Medical electrical equipment: Particular requirements for basic safety and essential performance of surgical, cosmetic, therapeutic and diagnostic laser equipment'.<sup>6</sup> Under the previous MDD, EN 60601-2-22:2013 was harmonised with the Directive, meaning that if a laser is deemed to have passed the tests against the requirements of EN 60601-2-22:2013, then by presumption of conformity, the equipment will also satisfy the relevant sections of the new MDR.

## EU standards and Brexit

The UK's membership of the International Standards Organisation (ISO)<sup>7</sup> and International Electrotechnical Commission (IEC),<sup>8</sup> will be unaffected by the UK leaving the EU.<sup>9</sup> The British Standards Institute

## KEY abbreviations:

- **British Medical Laser Association (BMLA)** – society for medical lasers in the UK.
- **British Standards Institute (BSI)** – the UK National Standards Body, holds the UK membership of CENELEC, CEN, ETSI.
- **European Committee for Electrotechnical Standardization (CENELEC)** – is responsible for standardisation in the electrotechnical engineering field.
- **European Committee for Standardization (CEN)** – one of three EU organisations (with CENELEC and ETSI) who are responsible for developing and defining voluntary standards at European level.
- **European Medical Device Regulation (MDR)** – previously the Medical Device Directive or MDD. This comprises requirements that relate to the safety and performance of medical devices.
- **International Electrotechnical Commission (IEC)** – prepares and publishes international standards for all electrical, electronic and related technologies.
- **International Standards Organisation (ISO)** – independent, non-governmental international organization with a membership of 162 national standards bodies.

(BSI),<sup>10</sup> as the UK National Standards Body, will continue its work developing and publishing British Standards and there will be no change in this activity. At a European level, the BSI holds the UK membership of the three European standardisation organisations: the European Committee for Electrotechnical Standardization (CENELEC),<sup>11</sup> the European Committee for Standardization (CEN),<sup>12</sup> and the European Telecommunications Standards Institute (ETSI).<sup>13</sup> CENELEC and CEN are private organisations outside of the EU, responsible for coordinating the work of 34 countries in producing and circulating European EN Standards. Post-Brexit, the BSI's membership will continue as normal in making and publishing standards and it is the organisation's ambition for the UK to continue to participate in the development of European Standards through full membership of CENELEC and CEN. Since CENELEC and CEN are independent from political authorities, BSI's aspirations are unaffected by Prime Minister Theresa May's announcement on January 17 2017 that the UK will leave the Single Market.<sup>9,14</sup>

## New EU regulations

New regulations were formally published in May 2017 and will replace the current Directive (93/42/EEC) as well as the Active

Implantable Medical Device Directive (90/385/EEC).<sup>4</sup> The new Medical Device Regulation (MDR), which applies fully from May 2020, will bring more scrutiny of technical documentation and address concerns regarding the assessment of product safety and performance by placing stricter requirements on clinical evaluation and post-market surveillance. It also requires better traceability of devices through the supply chain.

Therefore, irrespective of whether a medical intervention is intended or not, all devices emitting infrared, visible or ultraviolet radiation, including coherent and non-coherent sources, intended for use on humans, will fall under the new MDR.<sup>4</sup> One of the key objectives of the new MDR will be 'To give patients, consumers and healthcare professionals confidence in the devices they might use every day'.<sup>15</sup> An important consequence of the new MDR will be the obligation that professional cosmetic and consumer lasers and ILS devices that are not currently sold as medical devices will be reclassified. This means they will be required, amongst other obligations, to meet the conditions of quality assurance in production, clinical evidence of efficacy and safety, post-marketing surveillance and remedial action planning.<sup>4</sup>

### UK regulation of device manufacturing

The Medicines and Healthcare products Regulatory Agency (MHRA)<sup>16</sup> is responsible for the regulation of therapeutic products in the UK. Particular interventions are deemed to be a CQC 'regulated activity' when undertaken by registered healthcare professionals (HCPs), which are provided under The Health and Social Care Act 2008 (Regulated Activities) Regulations 2014.<sup>17</sup> For laser and ILS devices sold as non-medical, professional cosmetic treatment devices, it is the role of the Chartered Trading Standards Institute (CTSI), which is supported by Public Health England (PHE), an executive agency of the DoH,<sup>18</sup> to enforce the standards. The CTSI is a professional association which represents trading standards professionals working in local authorities, business and consumer sectors. However, lack of a national trade or professional body to monitor the cosmetic device industry means that public complaints against clinics or practitioners rarely result in successful enforcement or prosecution.

### CE marking

For medical and non-medical laser and light devices to be sold legally in both the UK and EU, they must be legitimately CE-marked.<sup>19</sup> Equipment bearing the CE symbol should indicate conformity with the relevant European Directive(s) such as the MDD.<sup>20</sup> CE-marked medical devices which meet the MDD also carry a four-digit reference number from which the Notified Body, member state and Directive can be traced.<sup>21</sup>

It is assumed by many practitioners who use laser and light devices that CE-marked equipment is compliant with the MDD, and the majority of devices are. However, some equipment, particularly if directly imported by individuals and not through a recognised supplier, can bypass testing requirements and carry only the Supplier Declaration of Conformity (SDoC) from the country of manufacture. A Declaration of Conformity states the name and address of the

### China Export mark

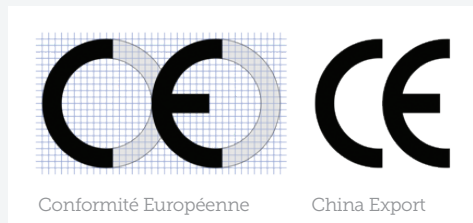


Figure 1: Comparison of the official CE mark and alleged 'China Export' mark.<sup>25</sup> The differences can be observed in the scaling of the marks and the spatial difference between the C and the E.

organisation responsible for the product, lists the EU Directives and standards it meets and is dated and signed by the organisation placing the product on the EU market. This means that the device may not necessarily carry a legitimate CE mark for the intended purpose of the device. Although not harmonised with the MDD, these SDoCs should ideally meet BS EN ISO/IEC 17050-1:2010<sup>22</sup> quality assurance and EU electrical safety standards, but for privately imported equipment, there is no monitoring or guarantee of conformity. In these instances, the obligation to ensure that the devices meet relevant EU Directives and standards is the responsibility of the individuals purchasing the device directly. In the eyes of the law, they are the importer and they are legally responsible for the safety of the product in its use on consumers.<sup>23,24</sup> It is widely accepted amongst informed practitioners that there is little to stop the sale (usually via the internet), of incorrectly or falsely CE-marked devices, which may lack adequate EU electrical safety compliance and medical device safety compliance. Most worryingly, such devices are readily available to purchase by those who may not be appropriately trained to operate such devices. Typically, such buyers often practise without professional body regulation, guidance or standards.

### Regulations of device use in the UK

We have explained the standards and regulations relating to laser and light device manufacturing, but it is important to also consider factors controlling the actual use of such devices. Up until October 2010, both HCP and non-HCP treatment providers using lasers and ILS devices in England were regulated by the CQC in facilities providing either treatment of disease, disorder or injury, non-surgical cosmetic interventions, or both.<sup>27</sup> The Care Standards Act 2000 included standards for various providers. These standards covered 'Prescribed Techniques and Prescribed Technologies' or 'P' standards for laser and ILS therapies. The 'P' standards provided the basis for the IHAS Essential Standards, which were updated in 2015/16 and relaunched by the British Medical Laser Association

Unfortunately, it has been alleged that a fraudulent and fake 'China Export' mark exists with a striking similarity to the official European CE marking (Figure 1). There is actually no official China Export mark.

Some people may get

confused with this as it implies that the product meets relevant Directives – this was raised in the European Parliament in 2008.<sup>25</sup> Consequently, many of the lower cost devices, that are regularly purchased online from countries in Eastern Asia/China and are typically used in beauty clinics rather than the medical sector, might not comply with any of the required standards for safe use. The CE mark may be no smaller than 5mm high and its proportions must follow the graduated drawing in Figure 1. If a Notified Body has been involved in the conformity assessment procedure, its four-digit identification number must also be displayed.<sup>26</sup>

(BMLA) in October 2016.<sup>28</sup> They reflect essential arrangements for safety and quality, as well as providing a useful template for facility audit by both clinic management and enforcement/regulatory bodies. In 2010, the UK Government deregulated the cosmetic sector in England with the repeal of the Care Standards Act 2000.<sup>29</sup> This has allowed anyone in England to purchase laser and ILS devices legally and deliver treatments with little or no training. There are also few restrictions on working from appropriate premises or enforcement of holding suitable insurance.

As a result of devolved UK government powers to Wales and Northern Ireland, while the repeal of the Care Standards Act 2000 took place in England, the provisions of the 'P' standards still apply in these areas. They are enforced by the Health Inspectorate Wales (HIW)<sup>30</sup> and the Regulation and Quality Improvement Authority (RQIA)<sup>31</sup> in Northern Ireland.

In certain regional areas of England, namely the London boroughs,<sup>32</sup> Birmingham,<sup>33</sup> Nottingham<sup>34</sup> and some Essex boroughs,<sup>35</sup> a licensing scheme exists for establishments that provide 'special treatments', which include; massage, electrolysis, laser and ILS therapies. In London, this licensing scheme is delivered under provisions of the London Local Authorities Act 1991.<sup>32</sup> The 'P' standards that apply in Northern Ireland and Wales and the 'Special Treatment Licence' provisions of some UK boroughs, are very similar in content.<sup>30,36</sup>

### Regulation in Scotland

On April 1, 2011, Healthcare Improvement Scotland (HIS)<sup>37</sup> took over the regulation of independent healthcare services in Scotland from the CQC. The current National Care Standards (NCS) of the Scottish Government for laser and light interventions were designed to improve and maintain the quality of delivered services, as required by the Regulation of Care (Scotland) Act 2001.<sup>38</sup> The key legislation is the Public Services Reform (Scotland) Act 2010<sup>39</sup> and the Scottish Statutory Instrument (SSI) relating to HIS (Requirements as to Independent Health Care Services) Regulations 2011.<sup>40</sup>

Until recently, HIS only regulated independent hospitals, voluntary hospices and private psychiatric hospitals. However, since April 1, 2016, HIS formally registers independent clinics in Scotland where services are provided by medical practitioners, registered nurses, midwives, dental practitioners and dental care professionals. It became an offence to operate an unregistered independent clinic in Scotland from April 1, 2017.<sup>41</sup>

The HIS regulations clearly state that a provider must have appropriate systems, processes and procedures for all aspects of care and treatment carried out by the independent healthcare service, including the use of Class 3B or Class 4 lasers and ILS equipment.<sup>37</sup> Moreover, the National Care Standards for Independent Specialist Clinics,<sup>42</sup> which only exists in Scotland, requires clinics to, 'Take account of all relevant legislation and current good practice guidelines', citing the MHRA guidance. Thus, the expectation is that independent clinics in Scotland using laser and light devices, must have access to the services of a certified laser protection adviser and work to a set of Local Rules detailing safety procedures as specified by the MHRA.<sup>1</sup>

### Training

Whilst there are standards and guidance documents relating to the use of laser and light devices, standards for the training of practitioners is less widely available.<sup>1,2,6,43</sup>

Training currently available for laser and light devices has variable

content, duration and quality. This may be due to the wide variation in equipment pricing in a highly competitive marketplace and a variety of distributors and outlets. Reputable distributors will provide online or face-to-face training, typically ranging from one to three days in duration and will offer users certification. Although there are many legitimate and useful manufacturer training courses, there are some that are not competence based, nor formally assessed, therefore the quality of such training is variable and difficult to align with academic standards such as those proposed by Health Education England (HEE), which is discussed below.

The standard BS EN 16844:2017 'Aesthetic medicine services – Non-surgical medical procedures'<sup>44</sup> was developed concurrently to the surgical standard (BS EN 16372:2014 'Aesthetic surgery services') by the CEN/TC 403 technical committee.<sup>45</sup> It was approved by national committees in January 2017 and was published on July 31. This British Standard provides recommendations for procedures for clinical treatment, including the ethical framework and general principles according to which clinical services are provided by all aesthetic practitioners. These recommendations apply before, during and after the procedure.

Outside London and some provincial councils with unitary powers to control certain cosmetic interventions through Special Treatments licensing, this non-surgical medical procedure standard provides an authoritative benchmark guide for local authorities in England seeking to ensure compliance under general safety legislation.

The use of laser and ILS in the UK is firmly established in both the private and public sectors, hospital departments, private aesthetic clinics and beauty salons. As we have seen, their use has been underpinned by British and international standards and guidance documents since the 1980s with the MHRA Guidance publication<sup>1</sup> and standards such as BS EN 60825-8:2006.<sup>2</sup> The current MHRA Guidance document<sup>1</sup> contains the 'Core of Knowledge' syllabus (Appendix C), which in the UK, remains a fundamental component of laser and light-related education and training in both the private and public sectors.

### Voluntary educational guidance

Guidelines are general rules, codes of conduct or statements that determine a course of action. Although not binding or legally enforceable, when issued by a professional authoritative body such as the BMLA or the European Society for Lasers and Energy Based Devices (ESLD), they may carry weight in litigation cases where they provide a 'benchmark' in establishing whether the actions of a professional could be deemed to be competent or not e.g. the Bolam test.<sup>46</sup> In November 2015, HEE published a recommended qualification framework for delivery of cosmetic procedures in two parts.<sup>47,48</sup> This publication provided the indicative content and knowledge elements of training and education for practitioners delivering a range of non-surgical interventions. The recommended framework developed by HEE has been adopted and is now owned by the newly formed Joint Council for Cosmetic Practitioners (JCCP). The JCCP remit is to develop and implement credible training frameworks and competencies, supported by registers of practitioners and training providers that are open to public scrutiny, by 2018.<sup>49</sup> However, the JCCP recognises that the registers will be voluntary for non-surgical cosmetic interventions and will therefore not be a legal requirement.<sup>45</sup>

This UK sector is currently well served by a significant number of credible, robust, academic programmes of study, ranging from Quality and Credits Framework (QCF) Level 3 to Level 7 in all laser and light

modalities listed in the HEE documents, namely: hair reduction, skin rejuvenation, tattoo removal, treatment of vascular and pigmented lesions, non-ablative and ablative therapies. The core HEE principles should be included within the programme specifications of credible training providers which include: patient assessment, informed consent, information governance and record keeping, ensuring that practitioners have a clear understanding of the requirement to operate from safe premises, infection control, treatment room safety and adverse incident reporting.

### Conclusion

Variations in UK regional Government policy have led to significant disparities in licensing and enforcement of controls over the use of lasers and ILS devices in the UK. The distinction between ‘medical’ and ‘cosmetic’ causes issues when assessing which agency is responsible for the enforcement of equipment standards. Equipment compliance standards are too easily avoided, mistaken or overlooked through internet purchase and weak enforcement, plus Chinese export marketing methods can create insecurity about the legitimacy of the CE marking on some devices.

Recently published surgical and non-surgical standards provide guidance for procedures for clinical treatment and should be used as reference documents for good practice in areas of England where no regulatory controls exist.

Learners in the UK have access to a range of robust accredited courses and qualifications with competencies that accurately assess the clinical knowledge and skills recommended within the HEE publications. Given the number of credible programmes that exist, it is beholden upon practitioners to continue their professional and personal development in this growing specialism to deliver high standards of treatment and patient care.



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