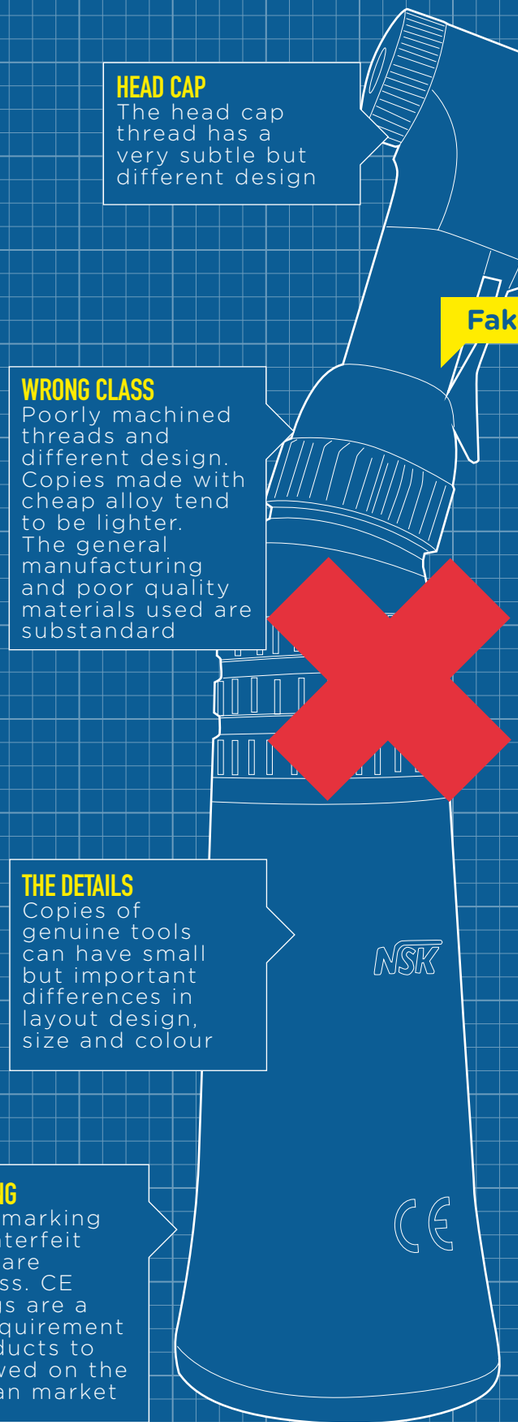
ILLUSTRATION: COREY JACKSON

STEMMING THE SPREAD OF COUNTERFEIT DENTAL DEVICES

Ineffective equipment poses risks to patient and user safety, and quality has a role to play to minimise it. Katrina Rozal looks at the dangers involved, and what the dental industry and the UK's products regulator are doing to curb the risks



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In January 2014, the UK government's Medicines and Healthcare products Regulatory Agency (MHRA) issued a safety alert to dental professionals, after a counterfeit dental handpiece (drill) shattered in a patient's mouth in November 2013. A subsequent investigation revealed that more than 110 counterfeit and non-compliant dental devices had been purchased by the then-directors of a group of dental surgeries, and distributed to their 14 practices. ➤

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"Most counterfeited devices in the UK are over-the-counter devices. However, we have identified a number of websites selling counterfeit dental equipment," a spokesperson for the healthcare regulator told *QW*. "Among the examples of dangerous dental devices we've seen is the portable X-ray unit, which was found to be non-compliant."

Tests revealed that the X-ray unit gave off elevated levels of radiation during use, posing health risks to both the operator and the patient. Counterfeit and non-compliant dental devices range from endodontic probes, intraoral cameras and syringes. Fake-branded handpieces and curing lights, which are used to cure fillings, are among the most dangerous dental counterfeit products due to potential structural failure, unstable and ineffectual curing, and the risk of electric shock. Cheap alloys in handpieces can bend or break after a few uses, or break during sterilisation. Counterfeit or non-compliant dental burs have been reported to shatter at high speeds, which could cause the patient to either swallow or inhale the fragments.

According to the MHRA, since 2015 more than 14,000 medical devices destined for dental surgeries in the UK were seized during enforcement operations targeting non-compliant and counterfeit dental equipment. About £150,000 of non-compliant dental devices have been seized since April 2015. Since that year, the MHRA has closed more than 140 online retailers, and there has been 92 compliance/enforcement investigations into dental practices, labs and general non-compliant dental devices. In 2014, the regulator seized 12,122 counterfeit and non-compliant dental devices, which included 24 X-ray machines, 683 curing lights and 384 handpieces.

The British Dental Industry Association (BDIA) has been working to stem the procurement of such devices through its Counterfeit and Substandard Instruments and Devices Initiative (CSIDI), which launched in 2014. The BDIA then partnered with the MHRA in its industry-wide campaign in 2016.

"It's about tapping into the demand issue because we know that is the most effective way of dealing with counterfeits"

Image source: NSK

"I think our main job is to raise awareness of this issue amongst the dental profession, and to encourage dental professionals that they should have robust procurement systems in-house so that they can ensure they're not buying this equipment," Edmund Proffitt, Chief Executive of the BDIA, told *QW*. "The estimated costs of seized devices shows a reduction over previous years, as the items seized in 2016-17 have been lower-value devices such as prophy cups and k-files. There's been a decrease in seizures of more expensive items, like dental drills. Over the last few years, the devices being seized are much simpler. It's not X-ray machines or curing lights.

"When looking at this issue against the background of all dental device purchases it is comparatively small, but it is important that we work with the dental profession to eradicate the possibilities of purchasing fake and non-compliant dental equipment."

Between April 2015 and March 2016, the MHRA seized 11,880 products with a value of £100,074. From April 2016 to September 2017, the 41,170 products seized totalled a value of £49,610.

"Dental handpieces have been a particular problem with counterfeit [medical devices] and so we've worked with BDIA to raise awareness amongst the [dental] profession about the problems that are out there, to really encourage people to use trusted suppliers. The BDIA's website has a list of approved suppliers, to help people make sure they are buying from people that understand the issue about counterfeits and non-compliant devices," Graeme Tunbridge, Group Manager – Devices Regulatory Affairs at the MHRA, told *QW*.

"It's about tapping into the demand issue, because we know that is the most effective way of dealing with counterfeits. You can shut down websites and take down things on Amazon and eBay, but ultimately the best way of addressing the problem is to stop demand."

Making the grade

Dental equipment must fulfill several requirements to be fit for purpose. In Europe, all medical devices must comply with the Medical Device Directive (MDD) to receive the CE mark. The directive sets out classifications and conformity assessments for all medical equipment, from pacemakers and lung ventilators to surgical clamps. The CE marking is a legal requirement for products to enter the European market. It verifies that a device has passed all conformity assessments and, depending on the risk classification of the device, by a Notified Body (an independent organisation registered with the government) such as the British Standards Institute (BSI) and LRQA, if required.

"The Medical Devices Directive effectively sets out the requirements of the quality system, [and is] the law, which everything must comply to," said Proffitt. "It is actually just being replaced, as we speak, by the new Medical Device Regulations. So there are very strict European regulations that govern all medical devices. They're pertinent to whoever you're talking to on all medical devices, not just dental."

The new regulation, which came into effect on 25 May 2017, requires stricter controls on high-risk devices (such as implants), tighter rules on clinical trials, tougher standards for Notified Bodies that approve the marketing of medical devices, and a new European database of medical devices. Manufacturers will have until 2020 to transition to the new regulation.

A key requirement of the legislation is a comprehensive quality management system that allows manufacturers to ensure best practices in the design, production, installation and servicing of medical devices and related services. The standard: ISO 13485, Medical devices – Quality management systems – Requirements for regulatory purposes, provides a practical foundation to fulfill the legislation.

The medical devices management system standard plays a role in mitigating the production of medical products that are not fit for purpose.

"[ISO 13485 is] a quality management system framework that integrates international regulations within it, so throughout the text of [the standard, manufacturers] are being kindly reminded about the responsibility to understand core regulatory requirements of a variety of international markets," said James Pink, CQP MCQI, Vice President, Europe, Medical Devices at NSF Health Sciences.

In the UK, the purchase of dental equipment is done by either an individual dental surgery practice or, more commonly, delivered through corporate dental practice groups such as Bupa.

"Dental professionals are responsible for purchasing direct from suppliers," said Proffitt.

"There's generally no NHS involvement, and that's why the CSIDI campaign is unique ➤

"[ISO 13485 is] a quality management system framework that integrates international regulations within it"

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because we're dealing with around 11,000 separate private company purchasers, and not 400 to 500 trusts within the NHS supply chain."

The supply chain and where it can go wrong

According to the BDIA, around 80 per cent of dental products in the UK are imported. Europe is a primary source for these dental devices. Legitimate products in the supply chain are produced by dental manufacturers who conform to the Medical Device Directive and recognised quality management systems. The bulk of the products have to be scrutinised by a Notified Body. The device is then sold directly by the manufacturer, an agent, distributors or sellers.

"There are quite a few distributors and retailers in the dental industry," said Proffitt. "We have over 120 members in our association, and that's a combination of manufacturers and distributors. They will all be selling equipment that has relevant CE marking, audit trails and device identifiers."

According to the BDIA, illegitimate dental devices primarily flow through the online marketplace and can surface at dental exhibitions. Fake or non-compliant items are sold online from overseas suppliers or from middlemen in the UK, who bring in unverified products in bulk and sell them through a website.

"We understand that the bulk of the counterfeits are actually coming out of China," said Proffitt. "These counterfeits are produced and marketed around the world… A lot of them are available on all sorts of global websites."

Online retailer, Alibaba.com says that it has measures in place to combat the spread of counterfeit dental devices on the internet: "Alibaba.com prohibits the listings of unauthorised medical devices on our third-party marketplace. We have strict control mechanisms in place to ensure that authorised medical devices, including dental devices, meet relevant international standards. If a member provides false information or documents, Alibaba.com reserves the right to impose penalties and/or take legal action … IP rights' holders, ie those who own intellectual property, can file requests to take down infringing listings through the Alibaba Intellectual Property Protection Platform (IPP)… and AlibabaGroup will then take rapid action."

Dental exhibitions or conferences can also be a potential source of fake or non-compliant devices.

"Dentists like to go to trade shows and look and feel the equipment. You will sometimes get unscrupulous standholders at trade shows trying to sell this equipment as well," said Proffitt.

While it is a criminal offence to supply counterfeit medical devices, dentists in the UK cannot generally be legally prosecuted for using counterfeit equipment.

"The equipment a dentist chooses to use is based on their clinical judgement and needs. However, the deliberate use of non-compliant or fake dental devices can impact on their registration to practise," said Proffitt. They can be subject to a fitness to practise hearing from the General Dental Council (GDC). The GDC can suspend or remove a dentist's registration to practise.

"From the dentist's side, it's their actual professional registration that is at stake," he adds.

In August 2017, the GDC suspended a dentist for three months for buying counterfeit and non-compliant products. The dentist admitted to purchasing several handpieces from an online auction website. The equipment was seized after two inspections carried out by the MHRA.

Jonathan Green, Director of Fitness to Practise at the General Dental Council, told *The Dentist Magazine* at the time: "This case shows the importance of dentists and DCPs (dental care professionals) adhering to the standards around compliant dental equipment. Non-compliant equipment endangers the health of both the patient and those using it, and it is vital that all items meet safety requirements."

Preserving patient safety

The quality function is crucial in protecting patient safety and stemming the prevalence of counterfeit and non-compliant dental tools. Dentsply Sirona and Henry Schein are two well-known healthcare product manufacturers that embed the principles of quality in their businesses.

"From the dentist's side, it's their actual professional registration that is at stake"

Dentsply Sirona develops, manufactures and markets dental and oral health products. It has 15,000 employees, operates in more than 40 countries, and has a market presence in more than 120 countries. The company's manufacturing facilities and strategic sites are certified to ISO 13485, and it is the basis of Dentsply Sirona's quality management system.

"Dentsply Sirona identifies practices to aid in development and production of quality products," Hannah Seevaratnam, Director of Quality Systems, Quality & Regulatory at Dentsply, told *QW*. "This includes corporate-wide quality system software, a standardised design control process, root cause and risk management methods, and robust quality policies, and procedures and compliance to relevant international standards."

One example is the lock slide, which is a small stabilising component used in the clamping system of a contra-angle drill. It must operate under high loads that only few materials can withstand in the long term. The challenge required the component design to incorporate filigree, to offer the smallest possible treatment heads. Great care had to be taken in selecting the material and ensuring compliance with tolerance requirements during production.

"Every product model has its own requirements coming from the dentist and assistant elements, in order to realise different comfort requirements in the treatment room," said Thomas Nack, Head of the Design and Development of Dentsply Sirona treatment centres at the Bensheim site in Germany.

Design begins with the functional and aesthetic requirements of the customer and the market. Research is made into current trends and design developments. The functional and aesthetic design are greatly influenced by product managers. Designers, hardware and software developers design the details of the individual components. Symbols play a key role in the control system, and can sometimes require a longer development process due to consultations with dentists.

"Prior to the release of ➤

Counterfeit dental devices

Image: BDIA

POTENTIAL PROBLEMS

Risks from counterfeit and non-compliant dental devices

1. HANDPIECE
Issues: excessive vibration, disintegration, bearing failure
Risk: patient or user injury, ineffective during use

2. CURING LIGHT
Issues: wrong timer and light emission, dangerous charger
Risk: ineffective, electric shock from charger

3. ENDODONTIC FILE
Issues: failure during use
Risks: patient and user injuries, ineffective

DENTAL BURS
Issues: failure during use, breaking in patient's mouth
Risk: patient swallowing or inhaling fragments

X-RAY DEVICES
Issues: exposure to radiation, faulty electrical system
Risk: patient and user injury, electric shock

Image: Thinkstock

products, they are tested at various intervals," said Seevaratnam. "The processes are routinely audited for compliance."

Dentsply Sirona's measures to verify their products against counterfeit items range from visual inspections to disassembly, to testing of material make-up in order to verify an item's legitimacy. The company also works with regulatory agencies to raise reports of counterfeit items from customers.

"Our online monitoring programme monitors and addresses counterfeit offerings available on a variety of online marketplaces worldwide," said Seevaratnam. "In addition, Dentsply Sirona encourages our customers to report and return suspect products to us for analysis and testing. When counterfeit products are identified, we pursue the counterfeiters through strategic legal and regulatory action."

Henry Schein provides healthcare products to dental, veterinary and medical practitioners. It is a Fortune 500 Company and employs more than 22,000 people. The company has been recognised by the Ethisphere Institute, a research centre that promotes best practices in corporate ethics and governance, as 2017's World's Most Ethical Company.

"Our online monitoring programme monitors and addresses counterfeit offerings available on a variety of online marketplaces"

"Henry Schein operates in 34 countries and has implemented a rigorous supplier validation programme, to ensure we purchase high-quality and compliant dental instruments and devices," said Rüdiger Vogler, Director Quality and Regulatory Affairs Europe at Henry Schein.

"We have an in-house team of regulatory and quality professionals who work with manufacturers to certify that their business practices and processes comply with the standards set by medical healthcare products, Notified Bodies and Competent Authorities in the UK, the rest of Europe and the US. ISO 13485 and 9001 are the foundation of our quality management systems, to ensure that we maintain quality and regulatory compliance."

The Henry Schein UK quality team recently upgraded from ISO 9001:2008 to ISO 9001:2015, by implementing a thorough assessment of new requirements, a gap analysis, and transition training. It resulted in no non-conformities in the application of the new quality management standard.

Site visits and audits are part of how Henry Schein verifies that the healthcare products, devices and equipment it purchases are compliant. "We do not conduct business with manufacturers who do not comply with our guiding principles and policies, as well as those established by UK regulators," said Vogler.

In terms of the supply chain, three areas that require special attention from Henry Schein's regulatory and quality management teams include: increasing regulatory and compliance requirements, cold chain management and overcoming language barriers.

Henry Schein has a dedicated operational team that has been trained to identify counterfeit items. Suspect products are quarantined for further investigation with the manufacturer. When product quality issues are raised, the information is recorded and sent to the head office in Melville, New York. All reports are consolidated and analysed for trends. The company also reviews and monitors its processes routinely, and ensures that any updates to regulations or directives are reflected in their operations.

Henry Schein Dental UK is a member of the BDIA and supports the organisation's CSIDI campaign.

The good fight

The BDIA suggests that there are two main ways for the dental profession to mitigate the risks of purchasing and using counterfeit and non-compliant equipment: the purchasing process and identification.

The MHRA and the CSIDI encourages professionals with doubts about the authenticity of a device to report it online through the MHRA Yellow Card Scheme at gov.uk/yellowcard. The CSIDI campaign will continue to be a key platform in combatting the counterfeit trade.

Tunbridge from the MHRA told *QW* that from speaking with dental companies, "a couple [have] said… that they have seen a difference over the last few years when it comes to the presence of these things on the market." He adds: "So, whilst it's not, kind of, empirical evidence, it gives us confidence that we're doing the right thing."

NSF's Pink believes the best thing manufacturers can do to combat the counterfeit trade is to demonstrate the integrity of their own traceability systems, by applying Unique Device Identification to devices. "I would put a lot of emphasis on traceability, of Unique Device Identification itself, and a type of vigilance process… sort of a routine surveillance process that detects and reports any sources or potential sources of counterfeiting."

As demonstrated by Dentsply Sirona and Henry Schein, compliance and assurance are vital pillars in securing the safety of patients and dental device users. ■

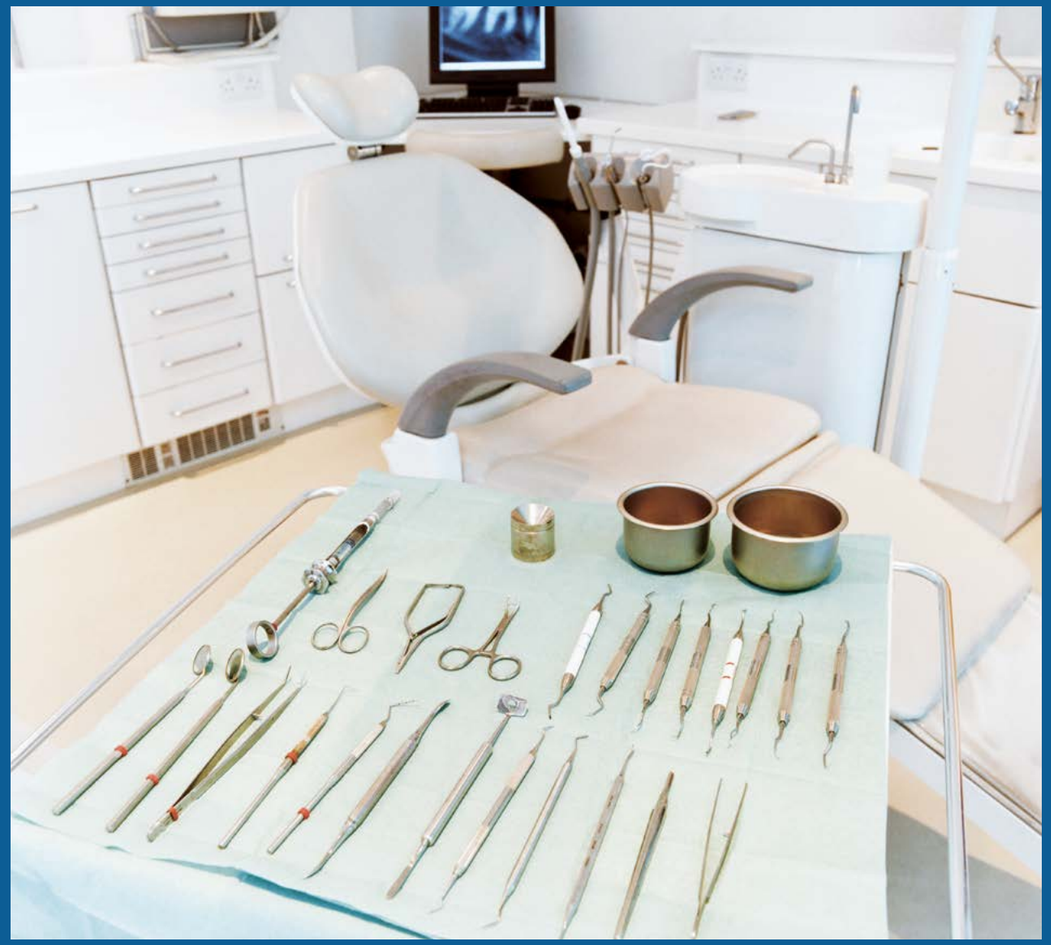

Image: Thinkstock

ANATOMY OF A MEDICAL DEVICE STANDARD

ISO 13485, Medical devices – Quality management systems – Requirements for regulatory purposes, defines the quality management requirements for organisations involved in any stage of a medical product's life cycle. This could be any organisation involved in the design and development, production, storage and distribution, installation, or servicing of a medical device.

Certification to ISO 13485:2016 allows manufacturers and their supply chain to safeguard the quality of their product. It offers a foundation for compliance with global regulatory bodies, including the European Medical Devices Directive, the European In Vitro Medical Devices Diagnostic Directive, the Canadian Medical Devices Regulations, and the international Medical Device Single Audit Program (MDSAP). The most recent version of the standard features enhanced interaction with international regulations.

"There are certainly aspects of many US and Japanese requirements that are now embedded within the text," said James Pink, CQP MCQI, Vice President, Europe, Medical devices at NSF Health Sciences. He adds that there is more focus on design reputation, appropriate acceptance criteria, statistical sampling, and general regulatory updates. Unique Device Identification (UDI) based on risk will be critical for preventing counterfeiting, and defining specific complaint handling and adverse event management. Anyone involved at the point of sale will gain more confidence about the originality of the products.

The health and safety organisation offers a CQI/IRCA-certified QMS Lead Auditor training course, based on ISO 13485:2016 and MDSAP. Pink developed the course with NSF colleagues, Kim Trautman, Executive Vice President, Medical Devices, and Brian Ludovico, Executive Director, MDSAP Regulatory Certification.

"I had developed a Lead Auditor course and we adapted it for Auditors who are, I guess, wanting to understand the MDSAP audit model," said Pink. "We wanted to ensure that our industry and audit organisations were adequately prepared to conduct audits that required knowledge of the five key regulatory jurisdictions, which [are] Australia, Brazil, Canada, Japan and the US."

More than 300 professionals have taken the course since its launch in January 2017.