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Medical Device Regulations for custom-made devices: Answers to a further ten important questions

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CPD questions

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Key points

- The withdrawal of the United Kingdom (UK) from the European Union (EU), the coronavirus disease 2019 (COVID-19) pandemic and the implementation of the Ireland/Northern Ireland Protocol have led to different parts of the UK following diverging medical device legislation.
- Custom-made devices in Great Britain (England, Scotland and Wales) must be manufactured in accordance with the Medical Devices Regulations 2002 (Statutory Instrument 2002/618) whilst those in Northern Ireland are subject to Regulation (EU) 2017/745 (EU Medical Device Regulation).
- Further changes to medical device legislation are expected, following the government response to the consultation on the future regulation of medical devices.

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Abstract

A custom-made device is a medical device that is 'intended for the sole use of a particular patient' made 'in accordance with a written prescription'. In a dental setting, common examples of custom-made devices include crowns, dentures and orthodontic appliances. Until fairly recently, dental professionals who manufactured custom-made devices within the European Union (EU) were required to do so in accordance with Council Directive 93/42/EEC (Medical Devices Directive [MDD]), which was given effect in the United Kingdom (UK) by the Medical Devices Regulations 2002 (Statutory Instrument 2002/618 [UK MDR 2002]). The MDD has since been replaced by Regulation (EU) 2017/745 (Medical Device Regulation [EU MDR]). However, the withdrawal of the UK from the EU, the coronavirus disease 2019 (COVID-19) pandemic and the implementation of the Ireland/Northern Ireland Protocol has led to different parts of the UK following different legislative frameworks. Dental professionals in Great Britain (England, Scotland and Wales) who manufacture custom-made devices must follow the relevant requirements of the UK MDR 2002 (although devices may be placed on the market in accordance with the EU MDR until 30 June 2024) whilst those in Northern Ireland are subject to the EU MDR. This paper provides answers to some key questions regarding the ways in which these legislative changes have impacted the provision of custom-made devices in the UK.

Introduction

A custom-made device is 'intended for the sole use of a particular patient' made 'in accordance with a written prescription' (see Table 1 for full definitions). Figure 1 provides examples of custom-made devices in a dental setting. Until 2021, custom-made devices manufactured within the European Union (EU) were governed by Council Directive 93/42/EEC (Medical Device Directive [MDD]).[1] The MDD is given effect within the UK by The Medical Devices Regulations 2002 (Statutory Instrument 2002/618 [UK MDR 2002]).[2]

In the years that followed the implementation of the MDD, incidents with sub-standard devices outside dentistry led to the need for more robust requirements.[3] On 5 April 2017, Regulation (EU) 2017/745 (Medical Device Regulation [EU MDR])[4] was published and introduced significant changes to EU medical device legislation. The EU MDR came into force on 25 May 2017 and was scheduled to replace the MDD on 26 May 2020, but on 23 April 2020 full implementation was deferred by one year (until 26 May 2021) by Regulation (EU) 2020/561 as a result of the coronavirus disease 2019 (COVID-19) pandemic.[5,6]

On 1 April 2019, in preparation for the UK's departure from the EU, the EU MDR was effectively transposed into UK legislation by the Medical Devices (Amendment etc.) (EU Exit) Regulations 2019 (Statutory Instrument 2019/791 [UK MDR 2019]),[7] an amendment of the UK MDR 2002, which was expected to take effect on the day the UK departed the EU.

Table 1 Definitions given in medical device legislation that are pertinent to this paper

	Great Britain	European Union and Northern Ireland
	The Medical Devices Regulations 2002 (Statutory Instrument 2002/618)[2] (as amended)	Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices[4]
Authorised representative	–	any natural or legal person established within the Union who has received and accepted a written mandate from a manufacturer, located outside the Union, to act on the manufacturer's behalf in relation to specified tasks with regard to the latter's obligations under this Regulation;
Custom-made device	a relevant device that is: (a) manufactured specifically in accordance with a written prescription of a duly qualified medical practitioner or a professional user which gives, under his responsibility, specific characteristics as to its design (b) intended for the sole use of a particular patient, but does not include a mass-produced product which needs to be adapted to meet the specific requirements of the medical practitioner or professional user	any device specifically made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications which gives, under that person's responsibility, specific design characteristics, and is intended for the sole use of a particular patient exclusively to meet their individual conditions and needs.
Fully refurbishing	–	for the purposes of the definition of manufacturer, means the complete rebuilding of a device already placed on the market or put into service, or the making of a new device from used devices, to bring it into conformity with this Regulation, combined with the assignment of a new lifetime to the refurbished device
Manufacturer	(a) the person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party (b) any other person who assembles, packages, processes, fully refurbishes or labels one or more ready-made products or assigns to them their intended purpose as a device with a view to their being placed on the market under his own name, apart from a person who assembles or adapts devices already on the market to their intended purpose for an individual patient	a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark
UK responsible person	a person established in the United Kingdom who acts on behalf of a manufacturer established outside the United Kingdom in relation to specified tasks with regard to the manufacturer's obligations under these regulations	–

The UK left the EU on 31 January 2020 and entered an 11-month implementation period (IP) the following day, during which EU legislation continued to apply in the UK.[8] On 8 December 2020, the UK MDR 2002 was further amended by the Medical Devices (Amendment etc.) (EU Exit) Regulations 2020, (Statutory Instrument 2020/1478 [UK MDR 2020]),[9] which revoked the provisions of the EU MDR and substituted 'exit day' for 'IP completion day'. The IP ended on 31 December 2020.[10]

Despite the UK's departure from the EU, one of the UK's four constituent countries, Northern Ireland (NI), remains in line with the EU legislation due to the Ireland/Northern Ireland Protocol, which was designed to avoid a hard border between NI and the Republic of Ireland.[11,12] Therefore, medical devices in Great Britain (GB) must conform to the relevant requirements of the UK MDR 2002 (as amended) while those manufactured in NI are subject to the EU MDR.[13] Alternatively, medical devices in GB may be manufactured in accordance with the EU MDR until 30 June 2024 (rather than 30 June 2023 as previously stated).[14]

An article published in the *British Dental Journal* in 2021,[15] and republished in *BDJ Team* in 2022,[16] provided answers to some key questions regarding the ways in which these legislative changes have impacted the provision of custom-made devices; this paper provides answers to a further ten questions concerning this topic.

1. What is the difference between an EU directive and an EU regulation?

The EU's constitutional basis is set out in treaties that establish their rules and objectives. These objectives are met by different types of legislative acts: regulations, directives, decisions, recommendations and opinions. A regulation automatically becomes law in all member states from the date that it is fully implemented. A directive sets requirements that must be met in all member states but does not dictate the means of achieving them and needs to be transposed into national law in each member state before it becomes enforceable. A decision only applies to certain individuals or organisations. Regulations, directives and decisions are binding; recommendations and opinions do not impose legislative obligations and are non-binding.

In terms of UK medical device legislation, an EU Directive and an EU Regulation continue to have relevance. Following the UK's departure from the EU, the one-year deferment of the full implementation of the EU MDR due to COVID-19 and the implementation of the Ireland/Northern Ireland Protocol, GB follows an EU Directive (the MDD, given effect by the UK MDR 2002) whilst NI follows an EU Regulation (the EU MDR).

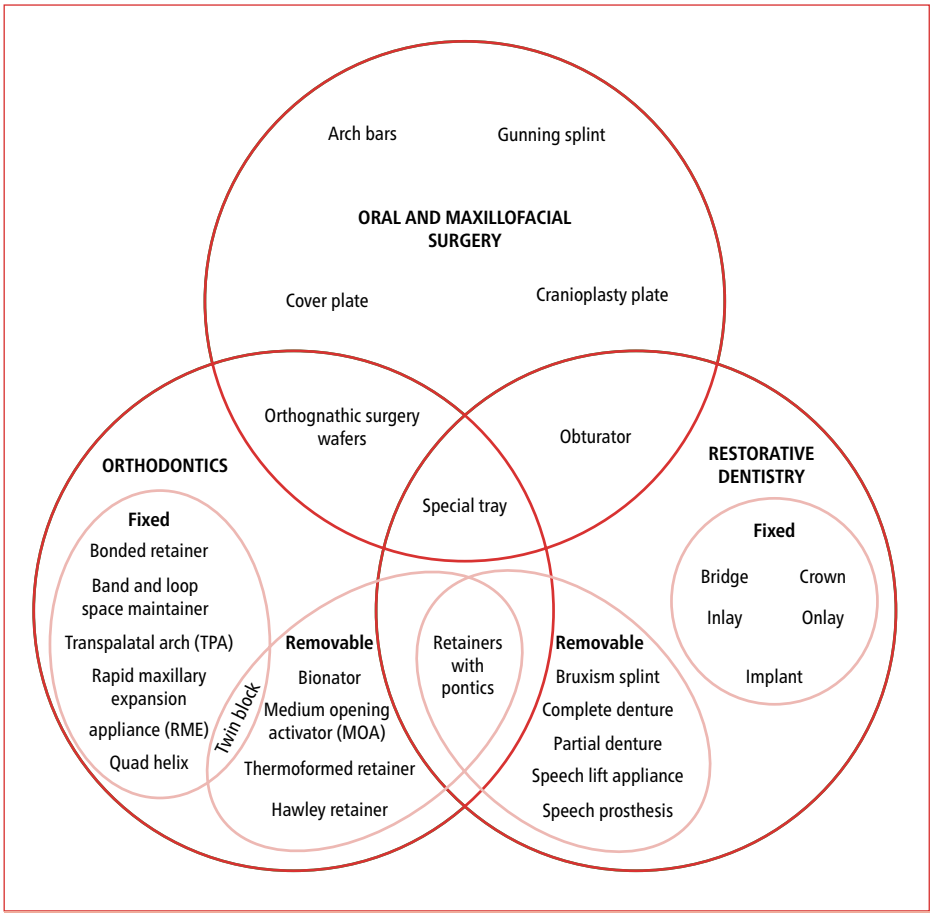

Fig. 1 Typical custom-made devices provided in a dental setting

Table 2 Custom-made dental device classification under UK and EU medical device legislation

Class I Generally considered low risk		Class IIa Generally considered moderate risk		Class IIb Generally considered potentially high risk	Class III Generally considered high risk
Rule 5			Rule 8		
Invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active medical device or which are intended for connection to a Class I active device			Implantable devices and long-term surgically invasive devices		
Used in the oral cavity as far as the pharynx			Placed in the teeth		
Transient	Short term	Long term			
Normally intended for continuous use for less than 60 minutes	Normally intended for continuous use for between 60 minutes and 30 days	Normally intended for continuous use for more than 30 days			Has a biological effect
Special tray	Arch bars	Bruxism splint	Crown	Dental implant	Dental implant (with a biological effect)
Occlusal registration rim		Denture	Bridge		
Prototype denture try-in	Buccinator flap appliance	Obturator	Inlay		
		Orthodontic appliance	Onlay	Dental implant abutment	
Intermediate orthognathic wafer	Final orthognathic wafer	Speech lift appliance	Veneer		
		Speech prosthesis			

Table 3 Obligations of the UK Responsible Person and the EU Authorised Representative

UK responsible person (Medical device manufacturers outside GB placing devices on the GB market) The Medical Devices Regulations 2002 (Statutory Instrument 2002/618)[2] (as amended) Regulation 7A(3)		EU authorised representative (Medical device manufacturers outside the EU or NI placing devices on the EU or NI market) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices[4] Article 11	
(a)	ensure that the declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer	(a)	verify that the EU declaration of conformity and technical documentation have been drawn up and, where applicable, that an appropriate conformity assessment procedure has been carried out by the manufacturer
(b)	Keep available for inspection by the Secretary of State a copy of the technical documentation, a copy of the declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements	(b)	Keep available a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificate, including any amendments and supplements, issued in accordance with Article 56, at the disposal of competent authorities for the period referred to in Article 10(8)
–		(c)	Comply with the registration obligations laid down in Article 31 and verify that the manufacturer has complied with the registration obligations laid down in Articles 27 and 29
(c)	in response to a request from the Secretary of State, provide the Secretary of State with all the information and documentation necessary to demonstrate the conformity of a device	(d)	in response to a request from a competent authority, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device, in an official Union language determined by the Member State concerned
(d)	forward to the manufacturer any request by the Secretary of State for samples, or access to a device and ensure that the Secretary of State receives the samples or has been given access to the device	(e)	forward to the manufacturer any request by a competent authority of the Member State in which the authorised representative has its registered place of business for samples, or access to a device and verify that the competent authority receives the samples or is given access to the device
(e)	cooperate with the Secretary of State on any preventive or corrective action taken to (f) cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices	(f)	cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices
(f)	immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated	(g)	immediately inform the manufacturer about complaints and reports from healthcare professionals, patients and users about suspected incidents related to a device for which they have been designated
(g)	terminate the legal relationship with the manufacturer if the manufacturer acts contrary to its obligations under these Regulations and inform the Secretary of State and, if applicable, the relevant notified body of that termination	(h)	terminate the mandate if the manufacturer acts contrary to its obligations under this Regulation

2. How does risk classification affect the legislative requirements for custom-made devices?

Under UK and EU legislation, medical devices are divided into four classes according to the potential level of risk associated with their use (I, IIa, IIb and III). Devices are categorised using classification rules, which are based on factors such as intended duration of use, intended purpose and invasiveness (Table 2). Some requirements for custom-made devices are driven by classification:

- Class I devices do not need to be provided with a statement[17]
- Class I or IIa devices can be provided without instructions for use if they can be safely used without them[1,4]
- Medical device manufacturers in NI and the EU are required to have a quality management system (QMS) 'that is proportionate to the risk class and the type of device'. (EU MDR Article 10[9]):

Class III custom-made implantable devices (such as dental implants with a biological effect) are subject to the conformity assessment set out in EU MDR Annex IX Chapter I or Annex XI Part A.[4] In GB, following the government response to the consultation on the future regulation of medical devices, it is expected that custom-made device manufacturers will be required to have a QMS in place. The government considers

that this QMS should be certified by a UK Approved Body in the case of Class IIb and Class III custom-made devices[18]

- Medical device manufacturers in NI and the EU are required to prepare a Periodic Safety Update Report (PSUR) (EU MDR Article 86). The PSUR needs to be updated at least biennially for class IIa devices and annually for class IIb and class III devices. A similar requirement is expected to be introduced for GB manufacturers.[18]

3. What are the requirements of GB-based manufacturers who place custom-made devices on the NI or EU market?

Under the Ireland/Northern Ireland Protocol, a medical device moving from or through Great Britain to NI is considered to be an import into the EU.[11] A GB-based manufacturer providing a medical device for a patient based in NI or the EU would constitute placing a medical device on the NI or EU market. Manufacturers outside the NI or EU who place a medical device on the NI or EU market must comply with the relevant requirements of the EU MDR and designate an Authorised Representative (as defined in Table 1) based in NI or the EU.[13] The obligations of the Authorised Representative are set out in EU MDR Article 11 (Table 3).

4. What are the requirements of non-UK manufacturers who place custom-made devices on the GB market?

A medical device manufacturer that is based outside the UK who places medical devices on the GB market must appoint a UK Responsible Person (UKRP; definition given in Table 1).[13] The UKRP is the UK equivalent of the EU Authorised Representative. A GB-based dentist who prescribes and fits a custom-made device that was constructed outside the UK may act as the UKRP for the overseas manufacturer. The obligations of the UKRP are set out in UK MDR 2002 regulation 7A(3) (Table 3).

5. Does a custom-made device prescriber need to be a healthcare professional?

Under the UK MDR 2002, a custom-made device must be 'specifically made in accordance with a written prescription of a registered medical practitioner, or any other person authorised to write a prescription…' and under the EU MDR, a custom-made device must be 'made in accordance with a written prescription of any person authorised by national law by virtue of that person's professional qualifications…' This means that a custom-made device prescriber does not necessarily need to be a healthcare professional. However, in terms of UK dental professionals, only dentists can prescribe custom-made devices, except in the case of complete dentures, which can also be prescribed by clinical dental technicians.[19]

Table 4 Packaging for non-sterile devices

Great Britain	European Union and Northern Ireland
Council Directive 93/42/EEC (Medical Device Directive [MDD])[1]	**Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices[4]**
Annex I Section 8.6	**Annex I Section 11.7**
Packaging systems for non-sterile devices must keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system must be suitable taking account of the method of sterilisation indicated by the manufacturer.	Packaging systems for non-sterile devices shall maintain the integrity and cleanliness of the product and, where the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system shall be suitable taking account of the method of sterilisation indicated by the manufacturer.

'In the years that followed the implementation of the MDD, incidents with sub-standard devices outside dentistry led to the need for more robust requirements'

6. Do sports mouth guards fall within the jurisdiction of medical device legislation?

A sports mouth guard can be defined as 'a resilient device or appliance placed inside the mouth (or inside and outside), to reduce mouth injuries, particularly to teeth and surrounding structures'.[20] The Medicines and Healthcare products Regulatory Agency (MHRA) states that 'mouth guards are only medical devices when intended for a specific 'medical' purpose, for example as a retainer following orthodontic treatment or for use in the treatment of sleep apnoea or for bruxism. In most other cases these products will be PPE [personal protective equipment], including those intended for sports purposes.'[21] Therefore, sports mouth guards are classed as PPE and are not governed by medical device legislation.

7. Do repairs to custom-made devices fall within the jurisdiction of medical device legislation?

The UK MDR 2002 defines 'manufacturer' as 'the person with responsibility for the design, manufacture, packaging and labelling of a device' or 'who assembles, packages, processes, fully refurbishes or labels' a device (UK MDR 2002 Regulation 2) and the EU MDR states that 'manufacturer' means a natural or legal person who manufactures or fully refurbishes a device...' (EU MDR Article 2[30]). As shown in Table 1, 'fully refurbishing'… means the complete rebuilding of a device… or the making of a new device from used devices…' (EU MDR Article 2[30]). A custom-made device repair does not constitute 'fully refurbishing' so is outside the scope of UK and EU medical device legislation.

8. Does medical device legislation make any stipulations regarding packaging for custom-made devices?

Custom-made devices in a dental setting are usually delivered in a non-sterile state. UK and EU legislation specify that packaging for non-sterile devices must maintain the integrity and cleanliness of the device. In cases where a device needs to be sterilised before use, such as arch bars and interocclusal wafers for orthognathic surgery facilitation, the packaging must minimise the risk of contamination from infectious material and also take the method of sterilisation into consideration (see Table 4).

9. Does the Medicines and Medical Devices Act have any implications for manufacturers of custom-made devices?

A significant proportion of UK medical device regulations are currently derived from EU legislation. The Medicines and Medical Devices Act 2021 passed into law on 11 February 2021 and is an important step towards the UK devising its own legislation.[22] The Act allows the amendment or supplementation of current human and veterinary medicine and medical device regulations (such as the UK MDR 2002). Medical devices are covered by Part 4 of the Act. The Act does not directly change the regulation of custom-made devices but allows the amendment of UK medical device legislation through secondary legislation (statutory instruments). Future statutory instruments, which have yet to be published, are expected to change the legislative requirements for custom-made devices.

10. What is the future expected to hold for the regulation of custom-made devices in the UK?

Between September and November 2021, the MHRA ran a consultation on proposed changes to UK medical device regulation, the government response to which was published on 26 June 2022.[18] The UK government intends to introduce the following requirements for custom-made devices:

- Clarification that the prescription for a custom-made device can be written in an electronic format
- More enhanced Annex I requirements. All medical devices manufactured in Great Britain must conform to the relevant Essential Requirements set out in MDD Annex I (as modified by the UK MDR 2002) while those manufactured in NI need to comply with the General Safety and Performance Requirements (GSPRs) set out in EU MDR Annex I. The MDD Annex I and EU MDR Annex I requirements are largely comparable, but the latter have been expanded and include the obligation to establish, implement, document and maintain a risk management system. The government intends to broadly reflect the GSPRs in the UK regulations, tailored to a domestic context, and also introduce a requirement for manufacturers to list component parts or ingredients that are known allergens or sensitisers
- The requirement for custom-made device manufacturers to implement a QMS, which should be certified by an Approved Body in the case of Class IIb and Class III custom-made devices
- More detailed requirements for the technical documentation that must be drawn up and kept by custom-made device manufacturers
- Enhanced post-market surveillance requirements: an obligation to produce periodic summary update reports or post-market surveillance reports. It is also expected that there will be a requirement for manufacturers to have measures in place, such as financial coverage, for providing recompense to those impacted by adverse incidents with medical devices.[18]

> *'Where a device needs to be sterilised before use, such as arch bars and interocclusal wafers, the packaging must minimise the risk of contamination and [consider] the method of sterilisation'*

Conclusion

This paper intends to raise awareness of the changes to medical device regulations in the UK and the EU and answer some key questions regarding the ways in which these changes have affected the provision of custom-made devices. This paper is not intended to be a substitute for reading the legislation itself.

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