Domanda n° 1

Nell'articolo 10, comma 3 del REGOLAMENTO (UE) 2017/745 DEL PARLAMENTO EUROPEO (E DEL CONSIGLIO del 5 aprile 2017 relativo ai dispositivi medici, che modifica la direttiva 2001/83/CE, il regolamento (CE) n. 178/2002 e il regolamento (CE) n. 1223/2009 e che abroga le direttive 90/385/CEE e 93/42/CEE del Consiglio) si richiamano gli obblighi generali dei fabbricanti nel rispetto dei requisiti di cui all'articolo 61 e all'allegato XIV. In che cosa consistono questi requisiti?

Domanda n2

Caratteristiche fisiche, meccaniche e cliniche del polietere-etere-chetone (PEEK) utilizzato per la realizzazione dei dispositivi medici odontoiatrici in implantoprotesi

Domanda 3

Tecniche di costruzione dei dispositivi medici odontoiatrici in metallo-ceramica

ESATTA

Medical Device Regulation: Requirements for Dental Professionals Who Prescribe and Manufacture Custom-Made Devices

device (CMD) is a medical device intended for the sole use of a particular patient. In a dental setting, CMDs include prosthodontic devices, orthodontic appliances, bruxism splints, speech prostheses and devices for the treatment of obstructive sleep apnoea, trauma prevention and orthognathic surgery facilitation (arch bars and interocclusal wafers). Since 1993, the production and provision of CMDs have been subject to European Union (EU) Directive 93/42/EEC (Medical Device Directive, MDD) given effect in the UK by The Medical Devices Regulations 2002 (Statutory Instrument 2002/618), and its subsequent amendments. Regulation (EU) 2017/745 (Medical Device Regulation, EU MDR) replaces the MDD and the other EU Directive pertaining to Medical Devices, Council Directive 90/385/EEC (Active Implantable Medical Device Directive, AIMDD). The EU MDR was published on 5 April 2017, came into force on 25 May 2017 and, following a three-year transition period was due to be fully implemented and repeal the MDD on 26 May 2020, but was deferred until 26 May 2021 due to the **coronavirus disease 2019** (COVID-19) pandemic.In the UK, in preparation for the country's planned departure from the EU, the EU MDR, with necessary amendments, was transposed into UK law (Medical Devices (Amendment etc.) (EU Exit) Regulations 2019, UK MDR). The UK left the Union on 31 January 2020 and entered a transition period that ended on 31 December 2020, meaning that, from 1 January 2021, dental professionals in Great Britain who prescribe and manufacture CMDs are mandated to do so in accordance with the new legislation while Northern Ireland remains in line with the EU legislation and implementation date. This paper sets out the requirements that relate to the production and provision of CMDs in a UK dental setting.

Domanda n° 1

nell'articolo 62, comma 1 del REGOLAMENTO (UE) 2017/745 DEL PARLAMENTO EUROPEO (E DEL CONSIGLIO del 5 aprile 2017 relativo ai dispositivi medici, che modifica la direttiva 2001/83/CE, il regolamento (CE) n. 178/2002 e il regolamento (CE) n. 1223/2009 e che abroga le direttive 90/385/CEE e 93/42/CEE del Consiglio) si fa riferimento alle Prescrizioni generali relative alle indagini cliniche condotte per dimostrare la conformità dei dispositivi. Elencare i fini riportati alle lettere a, b e c .

Domanda n2

Caratteristiche fisiche e meccaniche delle resine composite indirette per CAD-CAM utilizzate per la realizzazione dei dispositivi medici odontoiatrici

Domanda 3

Tecniche di costruzione dei dispositivi medici odontoiatrici in disilicato di litio monolitico

Medical Device Regulation: Requirements for Dental Professionals Who Prescribe and Manufacture Custom-Made Devices

device (CMD) is a medical device intended for the sole use of a particular patient. In a dental setting, CMDs include prosthodontic devices, orthodontic appliances, bruxism splints, speech prostheses and devices for the treatment of obstructive sleep apnoea, trauma prevention and orthognathic surgery facilitation (arch bars and interocclusal wafers). Since 1993, the production and provision of CMDs have been subject to European Union (EU) Directive 93/42/EEC (Medical Device Directive, MDD) given effect in the UK by The Medical Devices Regulations 2002 (Statutory Instrument 2002/618), and its subsequent amendments. Regulation (EU) 2017/745 (Medical Device Regulation, EU MDR) replaces the MDD and the other EU Directive pertaining to Medical Devices, Council Directive 90/385/EEC (Active Implantable Medical Device Directive, AIMDD). The EU MDR was published on 5 April 2017, came into force on 25 May 2017 and, following a three-year transition period was due to be fully implemented and repeal the MDD on 26 May 2020, but was deferred until 26 May 2021 due to the **coronavirus disease 2019** (COVID-19) pandemic.In the UK, in preparation for the country's planned departure from the EU, the EU MDR, with necessary amendments, was transposed into UK law (Medical Devices (Amendment etc.) (EU Exit) Regulations 2019, UK MDR). The UK left the Union on 31 January 2020 and entered a transition period that ended on 31 December 2020, meaning that, from 1 January 2021, dental professionals in Great Britain who prescribe and manufacture CMDs are mandated to do so in accordance with the new legislation while Northern Ireland remains in line with the EU legislation and implementation date. This paper sets out the requirements that relate to the production and provision of CMDs in a UK dental setting.

Domanda n° 1

Nell'articolo 10, comma 8 del REGOLAMENTO (UE) 2017/745 DEL PARLAMENTO EUROPEO (E DEL CONSIGLIO del 5 aprile 2017 relativo ai dispositivi medici, che modifica la direttiva 2001/83/CE, il regolamento (CE) n. 178/2002 e il regolamento (CE) n. 1223/2009 e che abroga le direttive 90/385/CEE e 93/42/CEE del Consiglio) I fabbricanti conservano e mettono a disposizione delle autorità competenti la documentazione tecnica, la dichiarazione di conformità UE. Quali sono le variazioni apportate dal nuovo regolamento rispetto alla 93/42 CEE? Quale periodo è previsto per i dispositivi impiantabili?

Domanda n2

Caratteristiche chimico-fisiche dei cementi utilizzati per l'incollaggio delle sovrastrutture in zirconia

Domanda 3

Tecniche di costruzione dei dispositivi medici odontoiatrici in zirconia monolitica

NON ESTRATTA

The European Medical Device Regulation–What Biomedical Engineers Need to Know

The Medical Device Regulation (EU) 745/2017 (MDR) has replaced the medical device directives which were in place since the early 1990s. MDR introduces a number of changes of relevance to biomedical engineers who work in healthcare institutions or with medical devices. This includes changes relating to devices produced in healthcare institutions, custom-made devices, single use devices, devices without an intended medical purpose, clinical investigations and device traceability. There are also challenges in implementation of the MDR, with a shortage of available notified bodies needed to conduct conformity assessment, with a consequent risk of product unavailability. Understanding these changes is important as implementing new requirements in practice may require additional resources or the introduction of new processes or systems.

Domanda n° 1

il Governo, nell'esercizio della delega per l'adeguamento della normativa nazionale al regolamento (UE) 2017/745 del Parlamento europeo e del Consiglio, del 5 aprile 2017, al regolamento (UE) 2020/561 del Parlamento europeo e del Consiglio, del 23 aprile 2020, e al regolamento (UE) 2017/746 del Parlamento europeo e del Consiglio, del 5 aprile 2017. osserva, oltre ai principi e criteri direttivi generali di cui all'articolo 32 della legge n. 234 del 2012, altri principi e criteri direttivi Specifici . Quali sono e in cosa consistono?

Domanda n2

Caratteristiche fisiche, meccaniche e cliniche della poliamide impiegata per la realizzazione dei dispostivi medici odontoiatrici

Domanda 3

Tecniche di condensazione e cottura delle ceramiche dentali

NON ESTRATTA

The European Medical Device Regulation–What Biomedical Engineers Need to Know

The Medical Device Regulation (EU) 745/2017 (MDR) has replaced the medical device directives which were in place since the early 1990s. MDR introduces a number of changes of relevance to biomedical engineers who work in healthcare institutions or with medical devices. This includes changes relating to devices produced in healthcare institutions, custom-made devices, single use devices, devices without an intended medical purpose, clinical investigations and device traceability. There are also challenges in implementation of the MDR, with a shortage of available notified bodies needed to conduct conformity assessment, with a consequent risk of product unavailability. Understanding these changes is important as implementing new requirements in practice may require additional resources or the introduction of new processes or systems.