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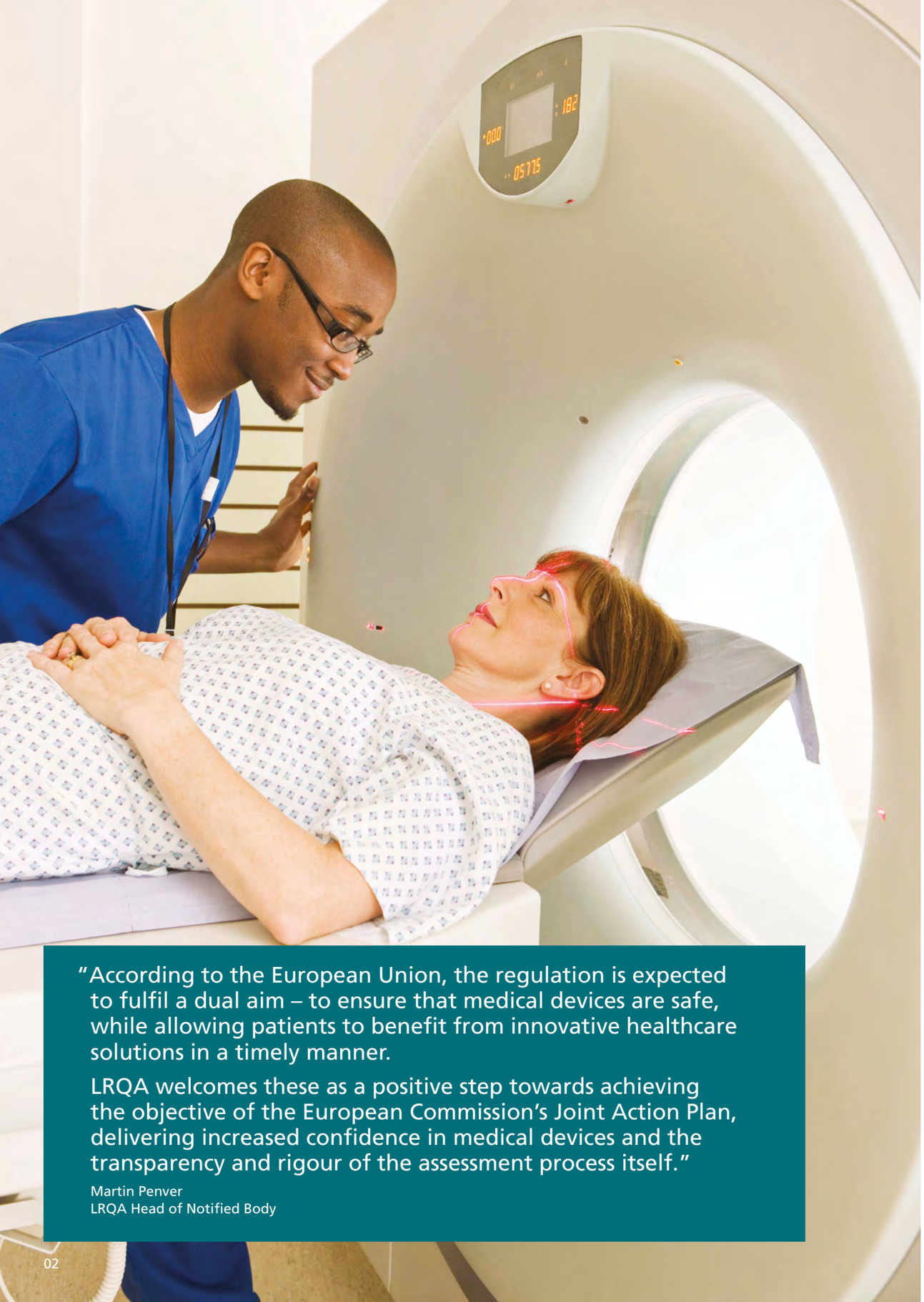
Improving performance,
reducing risk

Medical Device Regulation

Are you prepared for the changes?



"According to the European Union, the regulation is expected to fulfil a dual aim – to ensure that medical devices are safe, while allowing patients to benefit from innovative healthcare solutions in a timely manner.

LRQA welcomes these as a positive step towards achieving the objective of the European Commission's Joint Action Plan, delivering increased confidence in medical devices and the transparency and rigour of the assessment process itself."

Martin Penver
LRQA Head of Notified Body

Medical Device Regulation

Are you prepared for the changes?

The new Medical Device Regulation (MDR), published in May 2017, replaces the Medical Device Directive (MDD) 93/42/EEC6.

Why is the MDR necessary?

The European Union (EU) regulatory framework for medical devices consists of the Medical Device Directive (MDD) 93/42/EEC and Active Implantable Medical Devices (AIMD) Directive 90/385/EEC.

In the interest of simplification, both directives are combined under the MDR, which is introduced as a regulation instead of a directive, following a proposed revision by the European Commission on 26 September 2012.

Since the MDD and AIMD were first published in 1983 and 1990, constant scientific and technological progress, substantial deviations in the interpretation and application of the rules, and the perceived lack of transparency have all led to the existing directive coming under criticism in recent years.

A regulation was deemed the appropriate legal instrument as it imposes clear and detailed rules which do not give room for different interpretations by member states.

Moreover, the regulation ensures that legal requirements are implemented uniformly and at the same time throughout the union.

The choice of a regulation, however, does not mean that decision-making is centralised, and member states remain responsible for the implementation of the regulation in their state.

The text for the new regulation was published in the official journal of the European Union on 5 May 2017.

What does the new MDR aim to achieve?

The new regulation – known as (EU) 2017/745 – aims to overcome perceived flaws and divergences in order to further strengthen patient safety via a robust, transparent and sustainable regulatory framework that is 'fit for purpose'.

The European Commission has changed the requirements with the anticipation of achieving three key objectives:

- To give patients, consumers and healthcare professionals confidence in the devices they might use every day
- To allow industry to bring safe, effective and innovative products to market quickly and efficiently
- To increase the availability of innovative companies to attract investors, estimate costs and anticipate procedures.

What's new?

The MDR introduces a number of changes, some of the key ones being:
– Scope of regulated medical devices
– Pre-market scrutiny procedure
– Person responsible for regulatory compliance
– Identification and traceability
– Vigilance and market surveillance
– Supervision of Notified Bodies
– Clinical investigations and evaluation
– Timetable for introduction and transition.

Scope of regulated medical devices

The regulation clarifies and expands the scope of regulated medical devices and comprises:
– The inclusion of AIMDs combined into a single regulation
– Expansion of scope to include products with an aesthetic or non-medical purpose but which are similar to medical devices in terms of function and risk profile
– New classification rules for devices utilising nanomaterials and medical software
– Orally-administered products and requirements for conformity assessment
– Expansion of rule 17 to include devices manufactured utilising non-viable tissues or cells of human origin.

Pre-market scrutiny procedure

The European Commission proposed a 'scrutiny' procedure of a Notified Body's preliminary assessment report for implantable medical devices classified as class III by the Member State Authorities' Committee prior to the granting of CE marking certification. This also includes Class IIb (active devices intended to administer and/or remove a medicinal product from the body) (Rule 11).

The aim of this procedure is to improve the overall quality of Notified Bodies and their review of certain categories of high-risk class medical devices.

This mechanism foresees that the newly formed committee for member state authorities, the Medical Devices Coordination Group (MDCG), monitors applications being handled by Notified Bodies prior to the Notified Body issuing its certificate.

The MDGC shall select the applications they wish to review and comment upon the Notified Body's assessment and the technical documentation submitted by the manufacturer.

The CE marking would be dependent upon both the manufacturer and the Notified Body addressing any issues identified by the MDCG.

Person responsible for regulatory compliance

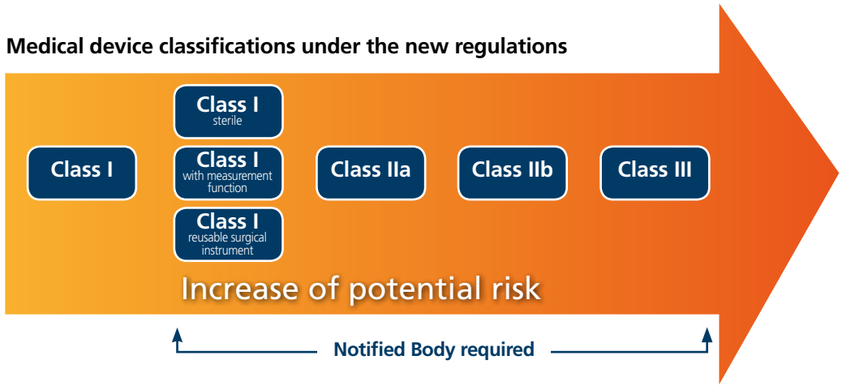
Manufacturers are required to have at least one person available that is responsible for regulatory compliance who possesses expert knowledge in the field of medical devices.

That expert knowledge can be proven by either of the following qualifications:

– Diploma, certificate or other evidence of formal qualification awarded on completion of a university degree or equivalent, in a relevant discipline. Additionally, at least two years of professional experience in regulatory affairs or in quality management systems relating to medical devices is required
– Five years of professional experience in regulatory affairs or in quality management systems relating to medical devices.

This person is responsible for ensuring device conformity is appropriately assessed before batches are released. They must also ensure that the technical documentation and declaration of conformity are prepared and kept up-to-date, and that vigilance reporting obligations are fulfilled.

Medical device classifications under the new regulations



Identification and traceability
The MDR stipulates medical device manufacturers must fit their devices with a unique device identification (UDI) and provide full details of the information that needs to be accessed through the UDI. The UDI system must be based on internationally recognised principles, including definitions that are compatible with those used by major trade partners. The exception to this requirement applies to custom made devices.

The benefits of having a UDI system include:
– Enhanced traceability, which should significantly improve the effectiveness of the post-market safety of medical devices
– Better incident reporting, targeted field safety corrective actions
– Improved monitoring by competent authorities
– Reduction in medical errors
– Reinforcement of the fight against counterfeit devices
– Improved purchasing and waste disposal policies and stock-management by health institutions and other economic operators.

The UDI system will be implemented gradually and proportionately according to the risk level (risk class) of the device. There is also a requirement that economic operators shall be able to identify who supplied them and to whom they have supplied medical devices. Additionally, there is an obligation for high-risk device manufacturers to make publicly available a summary of safety and performance, with key elements.

Vigilance and market surveillance
An electronic portal will be introduced where manufacturers can report serious incidents, safety corrective actions, field safety notices and periodic summary reports. The information will be automatically made available to the national authorities, enabling complications with medical devices to surface in a timely manner and contributing to a well functioning and robust vigilance system.

Device manufacturers will also have to report any statistically significant increase in the frequency or severity of incidents that are not individually serious incidents, but have an impact on the risk-benefit analysis.

Notified Bodies
The position of Notified Bodies in relation to manufacturers is significantly strengthened. They have a right and duty to carry out unannounced factory inspections and to conduct physical or laboratory tests on devices.

This mandates the current expectations that are within the recommendation, 2013/473/EU, and which most Notified Bodies have implemented under the controls of their respective competent authorities.

The regulation also requires rotation of the Notified Body's personnel involved in the assessment of medical devices at appropriate intervals to strike a reasonable balance between the knowledge and experience required to carry out thorough assessments.

Clinical investigations and evaluation

By setting higher standards of quality and safety for medical devices, the new MDR seeks to ensure, amongst other things, that data generated in clinical investigations is reliable and robust and that the safety of the subjects participating in a clinical investigation is protected.

Greater protections for patients participating in clinical investigations for medical devices are outlined in the new regulation. It is stated that the rules on clinical investigations should be in line with major international guidance in this field, such as the international standard ISO 14155:2011 (Clinical investigation of medical devices for human subjects – Good clinical practice).

Medical device manufacturers must demonstrate that their products have an acceptable benefit-to-risk ratio. For high-risk devices, manufacturers must conduct clinical investigations to demonstrate their product's safety and performance.

The regulation includes a provision to allow manufacturers of class III (highest risk) devices to consult with an expert panel to provide feedback on its clinical investigation strategy.

In addition, the regulation also provides criteria for, and restrictions on, clinical investigations, and allows for individual member states to further restrict certain practices within the scope of a clinical investigation.

To ensure synergies with the area of clinical trials on medicinal products, the regulation states that the electronic system on clinical investigations for medical devices should also be inter-operable with the EU database to be set up for clinical trials on medicinal products for human use.

Timetable for introduction and transition

Starting from 25 May 2017, the MDR has a transition period of three years. Manufacturers will need to update their technical documentation and processes in order to meet the requirements of the new regulation, which can be accessed here.

The MDR allows Notified Bodies to be designated and manufacturers to be assessed under the new regulation prior to the date of application. Notified Bodies can apply to be designated six months after its entry into force, and can issue certificates once re-designated.

By that time, devices in compliance with the new MDR can already be placed on the market, and certain requirements start to apply.

What you can do next

You can take certain measures to ease the introduction and implementation of the new regulation.

Plan for significant increases in both personnel and financial resource

Develop a customised action plan to cover the increase in both personnel and financial resource, to include securing regulatory affairs resources, such as the person responsible for regulatory compliance.

There is also significant increase in workload required under the new regulation, such as maintaining a summary safety and clinical performance report, plus keeping clinical evidence updated throughout the product lifecycle.

As well as updating technical files to meet the more stringent requirements of the new regulation, time will need to be put aside to ensure that all devices meet the new requirements for performance evaluation and clinical evidence as there is no 'grandfathering' clause in the new regulation.

There is also training resource (time and cost) to consider, both internal and external, to ensure compliance to the more stringent requirements under the regulation, including those related to material safety.

You also need to create standard operating procedures (SOPs) and training on how to handle unannounced Notified Body inspections of your business and your critical suppliers.

Realise the increased role of Notified Bodies under the regulation will extend approval times and costs

The additional requirements in the new MDR naturally mean a massively increased workload for Notified Bodies, and approval times may consequently increase as assessor diaries fill.

Costs will also increase due to longer review times for all devices (particularly high risk devices) and submission fees.

Look to transition your current devices to new certificates

The regulation does not just affect new devices. All of your current devices need to be re-evaluated and certified when the existing directive certificates expire.

Maintain an up-to-date quality management system (QMS)

Implement and maintain an up-to-date QMS to meet the requirements of the MDR that demonstrates your ability to provide medical devices that consistently meet regulatory requirements.

ISO 13845 is the most common harmonised standard used by medical device manufacturers to prove compliance, and the latest version, ISO 13485:2016, was published by the International Organization for Standardization (ISO) on 1 March 2016.

How can LRQA help?

Starting point
As there is no grandfathering for existing products, all manufacturers need to review their existing products against the requirements of the regulation.

You can begin by answering the following questions:
- Are you a manufacturer as defined in the directive or regulation and responsible for placing products on the market?
- Are your products medical devices?
- What is the classification and your chosen conformity route?

Application
Manufacturers that have not been assessed under the current MDD need to apply to a Notified Body for assessment. You will need to complete a simple form letting us know about your company and your products.

We will use this information to verify the requirements relating to your products and to work with you to determine the best options for conformity assessment.

Manufacturers that have already been assessed by a Notified Body will need to submit an application to have both their existing certified and current products assessed under the regulation.

Optional gap analysis
Unsure whether you are ready for the formal certification? Choosing our optional gap analysis will give you the confidence to go for certification.

This assessor-delivered activity offers the opportunity to focus on critical, high-risk or weak areas of your system in order to create a certifiable system. It can also look at how existing management systems or procedures can be used within your chosen standard.

Whether you are in the early stages of implementing your management system or looking to go for a 'dry run' before the assessment visit, the scope of the gap analysis can be decided with your business development manager or assessor and gives you more flexibility in choosing the scope and duration.

Training
LRQA's range of bespoke and packaged training services helps organisations take the uncertainty out of the new medical device regulations.

Our range of training courses include:
- Introduction to the new MDR
- Introduction to the new IVDR
- MDR Implementation
- IVDR Implementation

Review of technical documentation
As part of the assessment, the technical documentation of the product will be reviewed. These technical files will need to be reviewed before certificates can be issued for the manufacturer's products.

Certification
The certification assessment can, if requested, be used to assess the quality system against recognised QMS standards, such as ISO 9001, ISO 13485, the Canadian Medical Devices Conformity Assessment System (CMDCAS) and Medical Device Single Audit Program (MDSAP).

The assessor will establish that you have correctly identified which essential requirements apply to your products, fully integrated the requirements into the QMS, and taken the necessary steps to draw up the technical documentation.

Surveillance visits
Once approved, we will regularly review your system and sample technical files to ensure its ongoing effectiveness, and that you remain compliant with the regulatory requirements.

This gives you, and top management, the assurance that the management systems are on track and continually improving.

Classification Rules

NON-INVASIVE DEVICES

Rule 1
All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies

→ **Class I**

Rule 2
All non-invasive devices intended for channelling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class IIa:
- if they may be connected to an active medical device in Class IIa or a higher class

→ **Class IIa**

- if they are intended for use for storing or channelling blood or other body liquids or for storing organs, parts of organs or body cells and tissues

→ **Class IIa** except: blood bags → **Class IIb**

In all other cases

→ **Class I**

Rule 3
All non-invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or administration into the body

→ **Class IIb** unless: the treatment consists of filtration, centrifugation or exchanges of gas or heat → **Class IIa**

All non-invasive devices consisting of a substance or a mixture of substances intended to be used in vitro in direct contact with human cells, tissues or organs taken off from the human body or with human embryos before their implantation or administration into the body

→ **Class III**

Rule 4
All non-invasive devices which come into contact with injured skin or mucous membrane:
- if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates

→ **Class I**

- if they are intended to be used principally for injuries to skin which have breached the dermis or mucous membrane and can only heal by secondary intent

→ **Class IIb**

- in all other cases, including devices principally intended to manage the micro-environment of injured skin or mucous membrane

→ **Class IIa**

This rule applies also to the invasive devices that come into contact with injured mucous membrane

INVASIVE DEVICES

Rule 5
All invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active medical device or to a Class I active medical device:
- are in Class I if they are intended for transient use

→ **Class I**

- if intended for short-term use

→ **Class IIa** except: if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity → **Class I**

- if intended for long-term use

→ **Class IIb** except: if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity and are not liable to be absorbed by the mucous membrane → **Class IIa**

All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in Class IIa or a higher class

→ **Class IIa**

Rule 6
All surgically invasive devices intended for transient use

→ **Class IIa** unless they are:
- intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body
- intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system

→ **Class III**

- reusable surgical instruments

→ **Class I**

- intended to supply energy in the form of ionising radiation
- have a biological effect or are wholly or mainly absorbed
- intended to administer medicinal products by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application

→ **Class IIb**

Classification Rules

INVASIVE DEVICES

Rule 7
All surgically invasive devices intended for short-term use

→ **Class IIa** unless
- they:
  - are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body
  - are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system
  - have a biological effect or are wholly or mainly absorbed

  → **Class III**
- are intended to supply energy in the form of ionising radiation
- are intended to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines

  → **Class IIb**

Rule 8
All implantable devices and long-term surgically invasive devices

→ **Class IIb** unless
- they:
  - are intended to be placed in the teeth

  → **Class IIa**
- are to be used in direct contact with the heart, the central circulatory system or the central nervous system
- have a biological effect or are wholly or mainly absorbed
- are intended to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicinal products
- are active implantable devices or their accessories
- are breast implants or surgical meshes

  → **Class III**
- are total and partial joint replacements
- are spinal disc replacement implants and implantable devices that come into contact with the spinal column

  → **Class III**
- with the exception of ancillary components such as screws, wedges, plates and instruments

  → **Class IIb**

ACTIVE DEVICES

Rule 9
All active therapeutic devices intended to administer or exchange energy

→ **Class IIa** unless
- their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy

  → **Class IIb**

All active devices intended to control or monitor the performance of active therapeutic devices in Class IIb, or intended directly to influence the performance of such devices
All active devices intended to emit ionising radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance

→ **Class IIb**

All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices

→ **Class III**

Rule 10
Active devices intended for diagnosis and monitoring
- intended to supply energy which will be absorbed by the human body

→ **Class IIa** except
- devices intended to illuminate the patient's body, in the visible spectrum

  → **Class I**

- intended to image in vivo distribution of radio pharmaceuticals

→ **Class IIa**

- intended to allow direct diagnosis or monitoring of vital physiological processes

→ **Class IIa** unless
- they are specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of the central nervous system or diagnosis in clinical situations where the patient is in immediate danger

  → **Class IIb**

Active devices intended to emit ionising radiation and intended for diagnostic or therapeutic radiology, including interventional radiology devices and devices which control or monitor such devices, or which directly influence their performance

→ **Class IIb**

Rule 11
Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes

→ **Class IIa** except
- if such decisions have an impact that may directly or indirectly cause:
  - the death or an irreversible deterioration of the state of health

  → **Class III**
- a serious deterioration of the state of health or a surgical intervention

  → **Class IIb**

Software intended to monitor physiological processes

→ **Class IIa** except
- if it is intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient

  → **Class IIb**

All other software

→ **Class I**

ACTIVE

Rule 12
All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body

→ **Class IIa** unless
- this is done in a manner that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application

  → **Class IIb**

Rule 13
All other active devices

→ **Class I**

SPECIAL RULES

Rule 14
All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, with action ancillary to that of the devices

→ **Class III**

Rule 15
All devices used for contraception or the prevention of the transmission of sexually transmitted diseases

→ **Class IIb** unless
- they are implantable or long-term invasive devices

  → **Class III**

Rule 16
All devices intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses

→ **Class IIb**

All devices intended specifically to be used for disinfecting or sterilising medical devices
This rule does not apply to devices that are intended to clean devices other than contact lenses by means of physical action only

→ **Class IIa** unless
- they are disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing

  → **Class IIb**

Rule 17
Devices specifically intended for recording of diagnostic images generated by X-ray radiation

→ **Class IIa**

Rule 18
All devices manufactured utilising tissues or cells of human or animal origin, or their derivatives, which are non-viable or rendered non-viable

→ **Class III** unless
- where such devices are manufactured utilising tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable that are intended to come into contact with intact skin only

  → **Class I**

Rule 19
All devices incorporating or consisting of nanomaterial
- if they present a high or medium potential for internal exposure

  → **Class III**
- if they present a low potential for internal exposure

  → **Class IIb**
- if they present a negligible potential for internal exposure

  → **Class IIa**

Rule 20
All invasive devices with respect to body orifices, other than surgically invasive devices, which are intended to administer medicinal products by inhalation

→ **Class IIa** unless
- their mode of action has an essential impact on the efficacy and safety of the administered medicinal product and those that are intended to treat life threatening conditions

  → **Class IIb**

Rule 21
Devices that are composed of substances or combinations of substances that are intended to be introduced into the human body via a body orifice, or applied on skin and that are absorbed by or locally dispersed in the human body are:
- if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose
- if they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body

→ **Class III**

- in all other cases

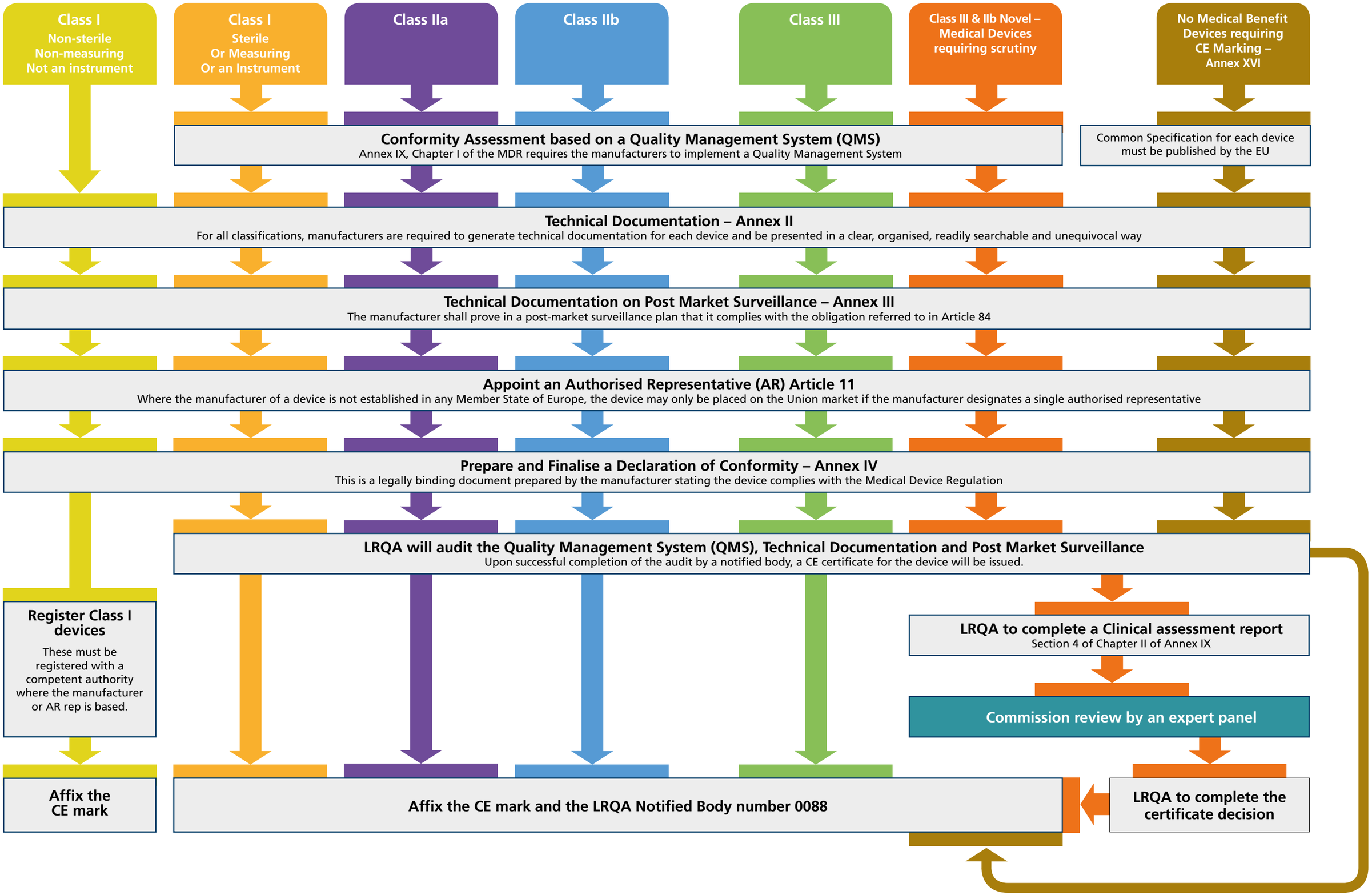
→ **Class IIb** except
- if they are applied on skin
- if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities

  → **Class IIa**

Rule 22
Active therapeutic devices with an integrated or incorporated diagnostic function, which significantly determinates the patient management by the device such as closed loop systems or automated external defibrillators

→ **Class III**

Conformity Assessment Procedures



Get it right the first time, on time

To win in the highly regulated and high stakes world of medical device manufacturing, it is crucial to beat the competition to the market, and minimise any potential losses from surprise product launch delays.

Our thorough yet streamlined approach ensures you get the right type of guidance at any stage of the product lifecycle, towards a timely market launch.

Our expertise

As a leading Notified Body with more than 20 years' experience in the medical arena, LRQA is actively shaping the medical regulations and associated harmonised standards through our experts' participation in the Medical Device Regulation (MDR) and In Vitro Diagnostic Device Regulation (IVDR) technical committees and associations, such as European Forum of Notified Bodies Medical Devices (NB-MED) and British In Vitro Diagnostics Association (BIVDA).

We also provide input to regulators such as the Medicines and Healthcare Products Regulatory Agency (MHRA) in the UK for the development of regulatory policies.

LRQA is currently working towards having a full scope as a Notified Body under the new MDR.

Reasons to choose LRQA

1. Globally recognised and accredited

LRQA has been a leading Notified Body for more than 20 years, and is independently accredited by the relevant accreditation bodies to provide CE marking to MDD 93/42/EEC and IVDD 98/79/EC. We are also accredited by United Kingdom Accreditation Service (UKAS) and Standards Council of Canada (SCC) to provide ISO 13485 certification, and by SCC and Health Canada to provide CMDCAS certification.

2. Best-in-class technical expertise

Applying LRQA's unique assessment methodology, our technical experts ensure they truly understand your long-term business objectives to reduce organisational risks, and enhance effectiveness, efficiency, and continuous improvement of your management systems.

3. Worldwide network of resources

With offices in 44 cities through which we serve over 50,000 clients in more than 120 countries, LRQA can meet you wherever you are.

4. Trusted organisation

With no shareholders of our own, we are independent and impartial in everything we do, and are committed to acting with integrity and objectivity at all times.

5. We care from the inside out

Our values of "We care, we share our expertise, we do the right thing" drives our approach to clients, how we care about the work we do, and our role as a trusted organisation.

6. When you buy our medical device assurance services, you're giving back to society

LRQA is part of the Lloyd's Register Group and at our heart sits a charity, the LR Foundation. Most organisations do something to make money but at Lloyd's Register, we make money to do something. As a percentage of our profits go towards the LR Foundation, every time you choose LRQA, not only are you getting best-in-class professional assurance services, but you are helping to make a difference to our world.

LRQA helps to unlock the power of your management systems to improve organisational performance and reduce risk.

To find out more about how LRQA can help you with your requirements, visit **lrqa.co.uk/mdr**, email **enquiries@lrqa.co.uk** or call **0800 783 2179**

Follow us:

Lloyd's Register Quality Assurance, 1 Trinity Park, Bickenhill Lane, Birmingham, B37 7ES, United Kingdom

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