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Letter from the Editor

Welcome to the second edition of the medical devices newsletter for 2012.

We are three quarters of the way through the year and 2012 is proving to be an eventful and interesting year for medical devices.

In this edition of our newsletter, we feature an introduction to the European Commission's proposals published on the 26th September 2012 for regulation of medical devices and *in vitro* diagnostic medical devices. The aim of the proposed regulations is to be more transparent and adaptable to scientific and technological progress. In addition, we have included an article presenting an overview of new European guidance relating to stand-alone software. This article highlights the types of stand-alone software that may qualify as a medical device and how these types of software may be classified. Also featured is an article providing background on Unique Device Identifiers (UDI) of medical devices and the ongoing work in Europe to develop a coordinated approach to UDI. A brief overview of the new Regulation relating to the utilisation of tissues of animal origin in medical device manufacture is also included as well as a short article highlighting the first meeting of the International Medical Device Regulators Forum (IMDRF) which took place earlier this year. A short overview of the European Commission's recent regulatory amendment which will restrict the sale and use of mercury containing measuring devices for industrial and professional uses is also outlined. A regulatory update has also been included at the end of this edition. As always, readers are encouraged to provide feedback, particularly in relation to articles that may be of interest, by contacting us at medicaldevices@imb.ie

CONTENTS

European Commission Adopts Proposals for New Medical Device Regulations

The European Commission adopted proposals for two new Regulations on the 26th September 2012. These Regulations are aimed to ensure patient safety, enhance transparency and be better adapted to facilitate scientific and technological progress.

The new rules aim to ensure that patients, consumers and healthcare professionals can reap the benefits of safe, effective and innovative medical devices.

The intention of these proposals is to replace the current Directives on medical devices (Directive 93/42/EEC) and active implantable medical devices (Directive 90/385/EC) with a single Regulation for medical devices. A Regulation for *in vitro* diagnostic medical devices is also proposed to replace the current Directive 98/79/EC for *in vitro* diagnostic medical devices.

The main elements of the proposals adopted by the European Commission include:

- Wider and clearer scope of EU legislation. A clearer and broader scope will help ensure that the safety and performance of these products are correctly assessed before they are placed on the European market;
- Stronger supervision of notified bodies by national authorities;
- More powers and obligations for notified bodies will be given to ensure thorough testing and regular checks on manufacturers are conducted, including unannounced factory inspections and sample testing;
- Clearer responsibilities and obligations for manufacturers, authorised representatives, importers and distributors will be defined and these will also be extended to diagnostic services and internet sales; An enhanced medical device database, providing comprehensive, public information on products available on the EU market is envisaged. Patients, healthcare professionals and the public at large will have access to the key data concerning medical devices available in Europe, allowing them to make better informed decisions;
- Better traceability of devices throughout the supply chain, will enable a swift and effective response to safety concerns. A Unique Device Identification system will be introduced to enhance traceability and post-market safety of medical devices, and will help to reduce medical errors and fight against counterfeiting;
- Stricter requirements for clinical evidence, to ensure patient and consumer safety;
- Adaptation of the rules to ensure technological and scientific progress. For example the adaptation of the safety and performance requirements applicable to new health technologies, such as software or nanomaterials used in healthcare;
- Better coordination between national surveillance authorities, to ensure that only safe devices are available on the European market;
- Alignment to international guidelines, to facilitate international trade.

The adopted proposals have been submitted to the European Parliament and the Council. In order to become binding Union law, Parliament and Council need to adopt the texts by ordinary legislative procedure.

The content of these proposals will be discussed in more detail in future editions of this newsletter. For further information relating to the revision of the medical devices directive, please use link below.

http://ec.europa.eu/health/medical-devices/documents/revision/index_en.htm

Stand-Alone Software MEDDEV 2.1/6

This article presents an overview of the new European guidance on what types of stand-alone software may qualify as a medical device and how such software should be classified.

The concept of 'stand-alone software' was first introduced into the medical devices legislation in Recital 6 of Directive 2007/47/EC, amending Directives 90/385/EEC and 93/42/EEC, which stated that "*it is necessary to clarify that software in its own right, when specifically intended by the manufacturer to be used for one or more of the medical purposes set out in the definition of a medical device, is a medical device.*" Furthermore, Recital 6 went on to explain that "Stand- alone software for general purposes when used in a healthcare setting is not a medical device." Subsequently the definition of the term "medical device", used in Directives 90/385/EEC and 93/42/EEC, was amended such that a medical device can be "*any instrument, apparatus, appliance, software, material or other article… specifically used for diagnostic and/or therapeutic purposes*".

GUIDANCE DOCUMENT WORKING GROUP AND PUBLICATION

In order to provide guidance to stakeholders on the implications of this change, a spin-off working group from the Classification and Borderline Working Group was formed in 2009 with the remit to develop and publish guidance on what stand-alone software would typically qualify as a medical device and how it would be classified. Software which is incorporated within a medical device is outside the scope of the guidance. If software is incorporated into a medical device rather than stand-alone software, it must be considered as part of that medical device. Software 'which drives a medical device or influences the use of a device, falls automatically into the same class as the device it drives.

The group consisted of representatives from:

- Competent Authorities (including the IMB),
- the European Commission,
- Medical Device Industry Associations and
- Notified Bodies.

MEDDEV 2.1/6 on the *Qualification and Classification of Stand-Alone Software* was published in January of this year.

SOFTWARE FROM THE INTERNET

Software, which meets the definition of a medical device and is made available over the internet, either directly, or via download or via commercial services providing *in vitro* diagnosis, fulfils the definition of being placed on the market and put into service and is therefore subject to the requirements of the medical device directives. The two key sections of the document relate to the qualification criteria for software to be considered a medical device and the subsequent application of the classification rules.

QUALIFICATION

Qualification Criteria for General Medical Devices

There are several criteria which a piece of stand-alone software must meet in order to be qualified as a medical device and/or an *in vitro* diagnostic medical device.

1. Firstly, a piece of software must be considered as a computer program for it to be considered a medical device. Image files and DICOM files are not considered to be computer programs but are digital documents and are not considered to fulfil the qualification criteria for a medical device.
2. For software to be considered stand-alone, it must not be incorporated in a medical device at the time it is placed on the market or made available. Software which is incorporated within a medical device, which drives or influences its use, is outside the scope of the guidance; such software falls automatically into the same class as that device and is subject to the requirements of the Directive.
3. The action which the software performs on the data is also considered a key qualification criterion. Where the software performs an action on data which is limited to storage, archival, communication, simple search or lossless compression then it is not considered to qualify as a medical device. However, software which is intended to create or modify med-

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ical information may be qualified as a medical device, where such alterations are made to facilitate the interpretative tasks and/or perceptual tasks performed by the healthcare professionals when reviewing medical information. Altering the representation of data for embellishment purposes does not make the software a medical device, however, where the alteration is for a medical purpose, it could be a medical device.

4. Furthermore, software must be used for the benefit of individual patients to be considered as a medical device; for example, software used for the evaluation of patient data to support or influence the medical care provided to that patient. However, examples of software which aggregates population data or is used for epidemiologic or registry studies are listed in the guidance as not being considered for the benefit of individual patients and therefore not considered a medical device.

5. Finally, to qualify as a medical device the software must be intended to be used for any of the medical purposes listed in Article 1(2)a of Directive 93/42/EEC. Where the software is not used for any of the purposes listed in Article 1(2)a but it is specifically intended to be used together with a medical device to enable that device to be used in accordance with its intended use, then the software is considered as an accessory to a medical device. As such, it shall be treated as a medical device in its own right. It is noted that only the intended purpose, as described by the manufacturer, is relevant for the qualification purposes and that the risk related to a malfunction of stand-alone software used within healthcare is, in itself, not a criterion for its qualification as a medical device.

Qualification Criteria for In vitro Diagnostic (IVDs) Medical Devices

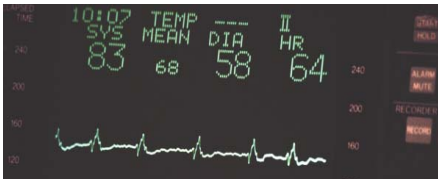
A piece of software which fulfils the definition of a medical device may also be considered as an *in vitro* diagnostic medical device if it is intended to be used for the purpose of providing information derived from the *in vitro* examination of a specimen derived from the human body.

- Where the software allows for an 'expert function' which provides information within the scope of the IVD definition, it may be considered an IVD. An expert function is defined as a software function that is able to analyse existing information to generate new specific information according to the intended use of the software.
- Where the information provided by the software is based on data obtained from IVD medical devices only, or from both IVD medical devices and general medical devices for the purpose of providing information for diagnosis, relating to a physiological or pathological state, or; congenital abnormality, or; to determine the safety and compatibility with potential recipients, or; to monitor therapeutic measures then it may be considered as an IVD medical device or an accessory.
- Stand-alone software that collects results obtained from one or several IVD devices (directly and/or manually), and transmits this information without modification to a centralised database (e.g. Laboratory Information Management System) or to healthcare providers is not considered an IVD medical device. To aid the qualification process, 6 step and 4 step decision diagrams are provided in the MEDDEV for general and *in vitro* diagnostic medical devices respectively.

CLASSIFICATION

Classification under the MDD

Active medical devices: In terms of classification, stand-alone software is considered as an active medical device and as such Rules 9, 10, 11 and 12 of of Directive 93/42/EEC are applied. The specific rule and therefore classification applied will depend on the intended purpose of the device and the nature of its action.



Class I stand-alone software with a measuring function: It is also noted that it is possible for Class I stand-alone software to have a measuring function.

Classification under the IVDD

Annex II list B IVD software: Concerning *in vitro* diagnostic medical devices; software intended for evaluating the risk of trisomy 21 is specifically mentioned in Annex II List B of Directive 98/79/EC.

Other IVDs: Other pieces of stand-alone software qualified as *in vitro* diagnostic medical devices are regulated according to relevant parts of Directive 98/79/EC.

Stand-alone software containing medical device & non-medical device modules: The document also acknowledges that some pieces of stand-alone software may break down into a significant number of applications, *i.e.* modules, which consist of both medical device and non-medical device modules and raises the question as to whether the whole product can be CE marked when not all applications have a medical purpose. The modules which are subject to the medical device Directives must comply with the requirements of the medical device Directives and must carry the CE marking. The non-medical device modules are not subject to the requirements for medical devices. It is the obligation of the manufacturer to identify the boundaries and the interfaces of the different modules and ensure that non-medical modules do not impair the specified performances of the modules which are subject to the medical device Directives.

List of Illustrative Examples

An annex to the document provides some illustrative examples of qualification for software used in the healthcare environment including: hospital information systems, decision support systems and communication systems. However, given the speed of technological progress in the software industry it is recognised that these examples will need regular updates and additions. These work items are planned to continue through the software working group. The guidance document may be downloaded from: **http://ec.europa.eu/health/medicaldevices/ files/meddev/2_1_6_ol_en.pdf**

Unique Device Identification (UDI) for Medical Devices

This article provides an overview of the Global Harmonisation Task Force (GHTF) UDI guidance document and also looks at how Europe intend to adopt a UDI system in the future.

BENEFITS OF A UDI SYSTEM

There are many benefits of having an effective UDI system throughout the whole supply chain (manufacturer, distributor, hospital and patient). For example, UDI improves traceability which assists in timely identification of devices, which in turn allows efficient completion of field safety corrective actions such as product recalls and investigations into reported incidents. In 2010, the IMB issued Safety Notice SN2010(09) Effective Traceability of Medical Devices to highlight the importance of traceability for medical devices. As well as offering traceability and a means of identification of medical devices for post market surveillance use, a UDI system may also help clinicians access critical patient safety information relating to a device and therefore assist clinicians in safely selecting the most appropriate device for a patient. Systems that will enable UDI will be critical for building effective national and regional registers which will be of benefit to patients, clinicians, regulatory authorities and manufacturers in enhancing patient and user safety.

CURRENT EUROPEAN REQUIREMENT FOR TRACEABILITY OF MEDICAL DEVICES

Currently, there is no harmonised traceability system for medical devices in Europe. As a result traceability systems that exist at national or regional level may not be compatible with each other, thereby limiting their effectiveness. A harmonised European traceability system would allow traceability of medical devices throughout their entire lifecycle and across all markets where the system is implemented. Currently efforts are being made at a European and global level to develop and implement a harmonised approach on traceability and to establish a globally accepted UDI system for medical devices.

The GHTF steering committee approved the 'Unique Device Identification (UDI) System for Medical Devices' guidance document in September 2011. The purpose of this guidance is to provide a framework for a UDI system such that, when implemented across different regions, a consistent global approach to UDI can be achieved.

The proposed new Medical Devices Regulation will introduce requirements for a system that will enhance the traceability of medical devices. Once this process is complete the Commission will be empowered to adopt detailed traceability requirements. It is envisaged that the European UDI system, when implemented, will be based on the global system as described in the GHTF 'Unique Device Identification (UDI) System for Medical Devices' document. Some of the main features of the UDI system described in the GHTF guidance document are summarised below:

FUNDAMENTALS OF A GLOBAL UDI SYSTEM

The UDI System will consist of three parts:

1. the development of the UDI using a globally accepted standard;
2. the application of that UDI on the label or on the device itself (UDI Carrier); and
3. the submission of appropriate information to a UDI Database.

Given the huge diversity of the medical devices available, a risk-based approach is used in the GHTF document and it is recommended that the requirements, where they are implemented, should be phased in starting with the highest risk class devices. In order for the UDI system to work effectively it is necessary to require all stakeholders to capture and store the UDI through distribution and use.

The following specific guidance is provided for the UDI, UDI Carrier and UDI Database:

UDI

- The UDI is a series of numeric or alphanumeric characters that is created through a globally accepted device identification and coding standard. It allows the unambiguous identification of a specific medical device on the market. The UDI comprises the Device Identifier and Production Identifier.
- The Device Identifier is a unique numeric or alphanumeric code specific to a model (or version) of medical device and that is also used as the "access key" to information stored in a UDI Database.
- The Production Identifier is a numeric or alphanumeric code that identifies the unit of device production. The different types of Production Identifier(s) include serial number, lot/batch number, manufacturing and/or expiration date.
- A UDI shall be assigned to the device itself or its package. Higher levels of packaging shall have their own UDIs.
- The manufacturer assigns the UDI to a device following the relevant coding standard.
- When a UDI is not assigned to the device at the level of its unit of use,

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then a Unit of Use (UoU) Device Identifier should be assigned, to associate the use of a device with a patient.

THE UDI CARRIER

- The UDI Carrier is the means to convey the UDI by using Automatic Identification and Data Capture (AIDC) and, if applicable, its Human Readable Interpretation (HRI).
- The UDI Carrier shall be on the label of the device, its package, or on the device itself, and on all higher levels of packaging.
- The UDI Carrier for low risk devices packaged and labelled individually does not need to be on its package but rather on a higher level of packaging, e.g. carton. However, when the user is not expected to have access (e.g., home user) to the higher level of packaging (e.g., carton), the UDI should be on its package.

THE UDI DATABASE

- The UDI Database (UDID) contains identifying information and other elements associated with the specific medical device.
- The manufacturer is responsible for the initial submission and updates to the identifying information and other device data elements in the UDID.
- The data in the UDID should be publicly available and free of charge.
- The database should allow for the linking of all the packaging levels of the product.
- The document also lists the core UDI Data Elements to be stored in the UDID.

ADDITIONAL INFORMATION

The GHTF document provides information for manufacturers on how UDI will be implemented for devices such as accessories and kits. There is also guidance regarding medical device reprocessing and own-brand labelling. The International Medical Device Regulators Forum (IMDRF) UDI work team, which has taken over the implementation of the UDI system from the GHTF *ad hoc* working group, is continuing its work to produce additional guidance on specific types of medical devices where additional guidance may be required, which will be included in future revisions of the GHTF document. Currently this work is being conducted through five consultation groups looking at IVD kits, non-IVD kits, capital equipment, integrated and stand-alone software and direct part marking in implants/surgical instruments.

NEXT STEP

The European Commission aims to issue a recommendation document for Member States who intend to develop their own UDI system. The recommendation will align as much as possible with the GHTF guidance document and will provide a general framework for a European UDI system. This recommendation will lay out basic principles which Member States should follow if they are considering implementing a national system for UDI in the short term in advance of the revised Regulations on medical devices and *in vitro* diagnostic medical devices. Ensuring that any national UDI system is developed using internationally agreed principles is critical to ensure that the data is useful and comparable. It is anticipated that this recommendation will be agreed by the end of 2012. Currently there is no national UDI system in place in Ireland.

http://www.ghtf.org/documents/ahwg/AHWG-UDI-N2R3.pdf

New Regulation on Medical Devices Containing Tissues of Animal Origin

The European Commission issued on 28th August 2012 published a new Regulation, 722/2012, on medical devices and active implantable medical devices manufactured utilising tissues of animal origin. The new Regulation replaces Directive 2003/32/EC and serves to meet the requirements laid down in Directives 93/42/EEC and 90/385/EEC, with respect to medical devices and active implantable medical devices manufactured using animal tissues. The full Regulation applies from 29th August 2013, except for Article 4 on notified body verification which applies from 29th August 2012.

From 29th August 2012, one year prior to full implementation of the Regulation, each Member State must verify that any notified body currently designated to conduct conformity assessments of medical devices manufactured using animal tissues has, and maintains, up-to-date knowledge to assess the conformity of such products. Member States have until 28th February 2013 to inform the EU Commission and other Member States of the outcome of their verification(s).

Whilst the Regulation reflects the general approach taken in Directive 2003/32/EC, there are a number of noteworthy additions, amendments and clarifications, and the key changes are as follows:

- Its scope has broadened to incorporate active implantable medical devices.
- For starting materials which have a TSE certificate of suitability issued by the European Directorate for the Quality of Medicines and Healthcare (EDQM), the notified body must now submit a summary evaluation report to their Competent Authority to be circulated to Member States for comments, where the total period of scrutiny is 4 weeks.

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Transition from the Global Harmonisation Task Force (GHTF) to the International Medical Device Regulators Forum (IMDRF)

The Global Harmonisation Task Force (GHTF) was established in 1992 in an effort to achieve greater uniformity between national and regional medical device regulatory systems, to enhance patient safety and increase access to safe, effective and clinically beneficial medical technologies around the world.

Since 1992, the working groups of the GHTF have produced guidance documents and have made efforts to facilitate an information exchange forum through which the experience of countries with established regulatory systems could be passed on to countries with developing medical device regulatory frameworks. http://www.ghtf.org/

In February 2011, the decision was made to build on the work of the GHTF with the establishment of a new voluntary group of medical device regulators from around the world to accelerate international medical device regulatory harmonisation and convergence. This group is called the International Medical Device Regulators Forum (IMDRF) and the inaugural meeting of this group took place in Singapore between 28th February and 1st March 2012. http://www.imdrf.org/

Plans were made at this meeting to develop this new forum and to transition several key work items from the GHTF by the end of 2012. Regulators from Australia, Brazil, Canada, Europe, Japan and the United States of America met to agree on the terms of reference for the IMDRF and to discuss proposals for new work items. Regulators from China and the Russian Federation also attended as observers, along with representatives of the World Health Organisation (WHO).

It was decided that the terms of reference for the IMDRF will be reviewed annually. The management committee agreed to develop a formal strategy for the management and maintenance of GHTF documents. The management committee also considered a request by industry for observer status on the management committee to which it was agreed that representative stakeholder delegations would be invited to attend nominated sessions of future meetings to provide an update on key issues.

At the inaugural meeting there were five key issues discussed. Firstly, a review of the National Competent Authority Report (NCAR) system was proposed with the intention to review the current arrangements of the NCAR exchange program and advise on opportunities for improvement and possible expansion of the system to allow for exchange of other types of information. Secondly, the roadmap for implementation of a Unique Device Identifier (UDI) system was discussed, which builds on earlier work from the GHTF. Thirdly, a work group will oversee the Medical Device Single Audit Program (MDSAP) in an effort to develop a standard set of requirements for auditing organisations performing regulatory audits of medical device manufacturers' quality management systems. The document produced will be applicable to competent authority auditing groups / inspectorates, as well as third party organisations that conduct such audits. This particular action will complement the current ISO13485 revision process under which the IMDRF seeks modifications to achieve a harmonised standard amongst its members. Fourthly, a list of standards used for medical device regulatory purposes that are recognised by the IMDRF is to be created. Finally, discussions took place on developing an international messaging standard that supports the electronic transmission of regulatory submissions. This work will define a common 'Table of Contents' for medical device regulatory submissions as a first step in defining a common data set.

Further information regarding the progress of the IMDRF can be found on their website http://www.imdrf.org

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- For starting materials which do not have a TSE certificate of suitability, the period of scrutiny for Member States to submit comments on the notified body's summary evaluation report remains at 12 weeks.
- The notified body must duly substantiate cases where comments from Member States are not taken into account in its decision-making process.
- More detailed evaluation criteria are in place for the notified body's assessment.
- There is a greater emphasis placed on the calculation of benefit:risk ratios.

Manufacturers with active implantable medical devices either on the market or about to be placed on the market before 29th August 2013, must apply to their notified body for a "Complementary" certificate, to show compliance with the new Annex I requirements in the regulation. Holders of EC design-examination certificates or EC type-examination certificates for active implantable medical devices using animal tissue will be allowed on the market until 29th August 2014.

New Restriction on Sale and Use of Mercury Devices for Industrial and Professional Uses

It is known that mercury and its compounds are toxic to humans, ecosystems and wildlife. High doses can be fatal to humans, but even relatively low doses can have serious adverse neurological impacts and have also been linked with possible harmful effects on the cardiovascular, immune and reproductive systems. Mercury is considered as a global persistent pollutant, circulating between air, water, sediments, soil and biota in various forms.

On September 19th 2012, the European Commission published an amendment to the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation, 1907/2006, which further restricts the sale and use of mercury-containing measuring devices. The REACH Regulation already prohibits the sale and use of mercury-containing measuring devices to the general public. The new amendment will restrict the sale and use of listed mercury-containing measuring devices including fever/temperature thermometers for industrial and professional uses.

The following mercury-containing measuring devices intended for industrial and professional uses cannot be placed on the market after 10th April 2014: (a) barometers; (b) hygrometers; (c) manometers; (d) sphygmomanometers; (e) strain gauges to be used with plethysmographs; (f) tensiometers; (g) thermometers and other non-electrical thermometric applications; (h) Mercury pycnometers and (i) mercury metering devices for determination of the softening point intended for professional and industrial uses.

The following mercury-containing devices for industrial or professional use are not subject to the new regulation and may continue to be placed on the market after 10th April 2014.

- Sphygmomanometers to be used in epidemiological studies which are on-going on 10th October 2012
- Sphygmomanometers to be used as reference standards in clinical validation studies of mercury-free sphygmomanometers
- Thermometers exclusively intended to perform tests according to standards that require the use of mercury thermometers until 10th October 2017
- Mercury triple point cells which are used for the calibration of platinum resistance thermometers
- Measuring devices that were more than 50 years old on 3rd October 2007
- Historically valuable mercury-measuring devices regarded as antiques or cultural goods, such as those displayed in public exhibitions for cultural and historical purposes.

The regulation containing the new requirements, Regulation 847/2012, will apply from 10th April 2014.
http://eurlex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:253:0001:0004:EN:PDF

Regulatory Update

UNIQUE DEVICE IDENTIFICATION (UDI) MEETING – JULY 2012

The European UDI (Unique Device Identifier) *Ad hoc* Working Group met in July 2012 in Brussels. The goal of the group is to review and discuss the development of a European UDI System to improve patient safety by enhancing the identification of devices, especially in the case of adverse events, and to facilitate traceability of devices in the event of a field safety corrective action. At the July meeting, an update was provided on the activity of the International Medical Device Regulators Forum (IMDRF) in relation to UDI. The European Commission has the lead role in the IMDRF UDI working team and it is anticipated that following the initial conclusions of the five consultation subgroups, a UDI roadmap may be agreed by the end of 2012. These five consultation sub-groups have been reviewing specific medical device types that may require additional UDI discussions such as capital equipment, *in vitro* diagnostic (IVD) Kits, non-IVD kits, software and direct part marking of implants / surgical equipment. The European Commission also presented a draft recommendation on a common framework for a unique device identification system in the EU and outlined how UDI may be incorporated into the future draft proposals for EU Regulations on medical devices.

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