Claiming Equivalence

The Regulatory Aspects

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By Royal Charter

bsi.

Topics Covered in this presentation;

- ❑ MDR Requirements
- ❑ General Principles of Equivalence under MDR
- ❑ Regulatory aspects of Equivalence based on Classification
- ❑ Clinical data for Equivalent devices
- ❑ Similar Devices
- ❑ Technical, Biological & Clinical
- ❑ Questions

Poll Question

How prepared are you with your clinical data?

- Very prepared
- Reasonably prepared
- A little prepared
- Not prepared at all

Poll Question

What is your level of knowledge of the requirements for clinical data under the MDR?

- Very Knowledgeable
- Reasonably knowledgeable
- Not very knowledgeable

A word of caution…

- Equivalence under the MDR continues to be a ‘hot topic’

- Equivalence must be considered on a case by case basis.

- The requirements around ‘claiming equivalence’ have been tightened under the MDR.

MDR Requirements

3. A clinical evaluation may be based on clinical data relating to a device for which equivalence to the device in question can be demonstrated. The following technical, biological and clinical characteristics shall be taken into consideration for the demonstration of equivalence:

— Technical: the device is of similar design; is used under similar conditions of use; has similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software algorithms; uses similar deployment methods, where relevant; has similar principles of operation and critical performance requirements;

— Biological: the device uses the same materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables;

— Clinical: the device is used for the same clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.

The characteristics listed in the first paragraph shall be similar to the extent that there would be no clinically significant difference in the safety and clinical performance of the device. Considerations of equivalence shall be based on proper scientific justification. It shall be clearly demonstrated that manufacturers have sufficient levels of access to the data relating to devices with which they are claiming equivalence in order to justify their claims of equivalence.

Annex XIV part A requires that the manufacturer should demonstrate that there are no clinically significant differences in safety or clinical performance for technical, biological and clinical characteristics.

Each of these characteristics should be considered in the context of ‘same’ and ‘similar’ as defined by the text.

Article 2 (48)

(48) 'clinical data' means information concerning safety or performance that is generated from the use of a device and is sourced from the following:

— clinical investigation(s) of the device concerned,

— clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated,

— reports published in peer reviewed scientific literature on other clinical experience of either the device in question or a device for which equivalence to the device in question can be demonstrated,

— clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up;

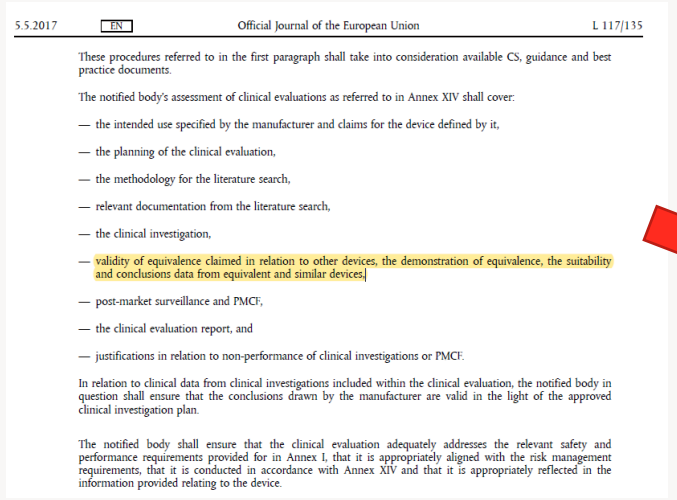
Within Article 2 of the MDR for the definition of clinical data we see that there is an allowance to use data from an equivalent device.

MDR Requirements Annex IX Chapter II

4.5. The notified body shall, in circumstances in which the clinical evidence is based partly or totally on data from devices which are claimed to be equivalent to the device under assessment, assess the suitability of using such data, taking into account factors such as new indications and innovation. The notified body shall clearly document its conclusions on the claimed equivalence, and on the relevance and adequacy of the data for demonstrating conformity. For any characteristic of the device claimed as innovative by the manufacturer or for new indications, the notified body shall assess to what extent specific claims are supported by specific pre-clinical and clinical data and risk analysis.

Similar scenario under Annex X 3 (d)

Annex IX Chapter II (Assessment of Technical Documentation) Section 4.5 requires the Notified Body to assess the clinical evidence when equivalence is claimed.



5.5.2017 EN Official Journal of the European Union L 117/135

These procedures referred to in the first paragraph shall take into consideration available CS, guidance and best practice documents.

The notified body's assessment of clinical evaluations as referred to in Annex XIV shall cover:

— the intended use specified by the manufacturer and claims for the device defined by it,

— the planning of the clinical evaluation,

— the methodology for the literature search,

— relevant documentation from the literature search,

— the clinical investigation,

— validity of equivalence claimed in relation to other devices, the demonstration of equivalence, the suitability and conclusions data from equivalent and similar devices,

— post-market surveillance and PMCF,

— the clinical evaluation report, and

— justifications in relation to non-performance of clinical investigations or PMCF.

In relation to clinical data from clinical investigations included within the clinical evaluation, the notified body in question shall ensure that the conclusions drawn by the manufacturer are valid in the light of the approved clinical investigation plan.

The notified body shall ensure that the clinical evaluation adequately addresses the relevant safety and performance requirements provided for in Annex I, that it is appropriately aligned with the risk management requirements, that it is conducted in accordance with Annex XIV and that it is appropriately reflected in the information provided relating to the device.

Annex VII – Requirements to be met by the notified body -Section 4.5.5. requires the NB as part of the clinical evaluation assessment to cover:

— validity of equivalence claimed in relation to other devices, the demonstration of equivalence, the suitability and conclusions data from equivalent and similar devices,

— post-market surveillance and PMCF,

Article 61 (4) EU 2017/745

4. In the case of implantable devices and class III devices, clinical investigations shall be performed, except if:

— the device has been designed by modifications of a device already marketed by the same manufacturer,

— the modified device has been demonstrated by the manufacturer to be equivalent to the marketed device, in accordance with Section 3 of Annex XIV and this demonstration has been endorsed by the notified body, and

— the clinical evaluation of the marketed device is sufficient to demonstrate conformity of the modified device with the relevant safety and performance requirements.

In this case, the notified body shall check that the PMCF plan is appropriate and includes post market studies to demonstrate the safety and performance of the device.

Article 61 (4) allows for Class III and Implantable devices claiming equivalence to be exempt from pre-market clinical investigations and directs the reader to Annex XIV Section 3 for more clarity.

Article 61 (5) EU 2017/745

5. A manufacturer of a device demonstrated to be equivalent to an already marketed device not manufactured by him, may also rely on paragraph 4 in order not to perform a clinical investigation provided that the following conditions are fulfilled in addition to what is required in that paragraph:

— the two manufacturers have a contract in place that explicitly allows the manufacturer of the second device full access to the technical documentation on an ongoing basis, and

— the original clinical evaluation has been performed in compliance with the requirements of this Regulation,

and the manufacturer of the second device provides clear evidence thereof to the notified body.

Section 5 although does not explicitly state this is related to class III or Implantable devices, it refers to paragraph 4 which **is** specific to this group of devices.

This paragraph calls out specific regulatory requirements to claim equivalence for these devices.

Annex XIV Part A (3)

3. A clinical evaluation may be based on clinical data relating to a device for which equivalence to the device in question can be demonstrated. The following technical, biological and clinical characteristics shall be taken into consideration for the demonstration of equivalence:

— Technical: the device is of similar design; is used under similar conditions of use; has similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software algorithms; uses similar deployment methods, where relevant; has similar principles of operation and critical performance requirements;

— Biological: the device uses the same materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables;

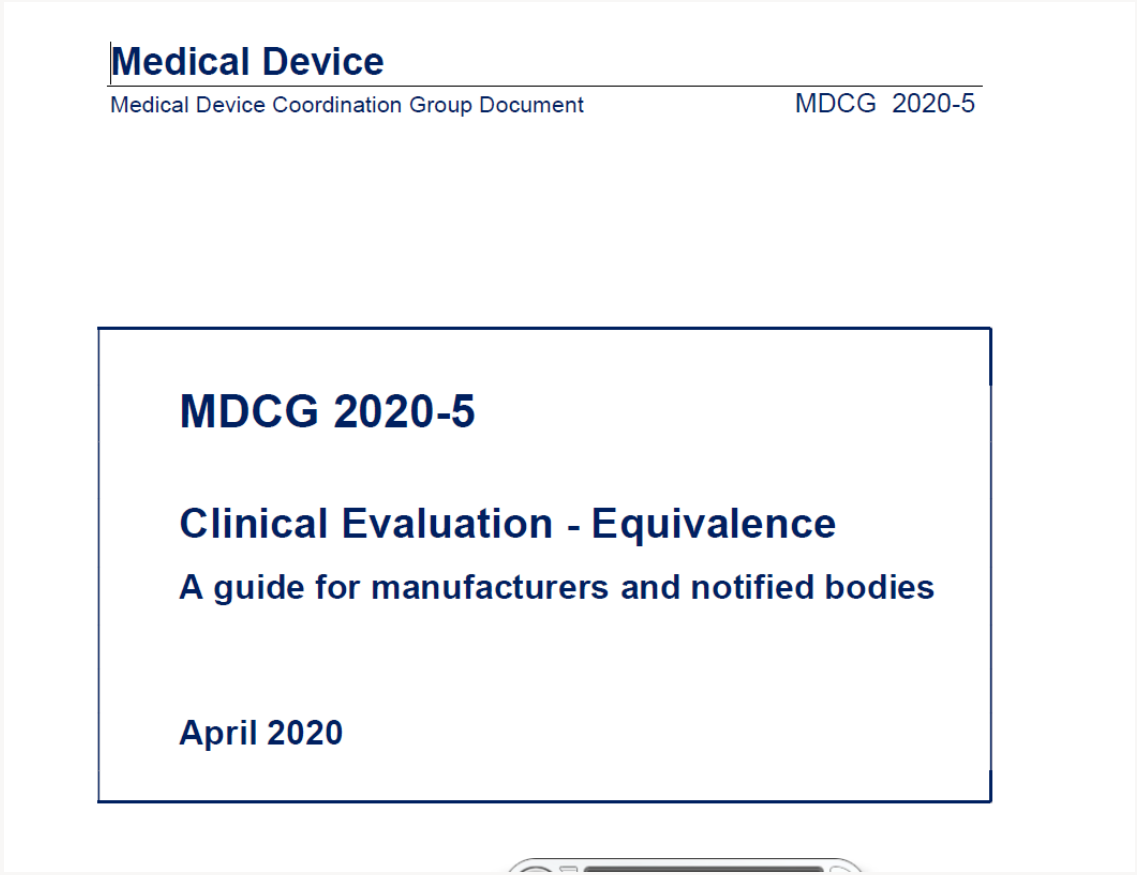
— Clinical: the device is used for the same clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.

The characteristics listed in the first paragraph shall be similar to the extent that there would be no clinically significant difference in the safety and clinical performance of the device. Considerations of equivalence shall be based on proper scientific justification. It shall be clearly demonstrated that manufacturers have sufficient levels of access to the data relating to devices with which they are claiming equivalence in order to justify their claims of equivalence.

The need to ensure Technical, Biological and Clinical characteristics are considered

Sufficient levels of access to data required.

MDCG 2020-5



The MDR does bring in new requirements in relation to the regulatory aspects of claiming equivalence and MDCG 2020-5 explains these in detail.

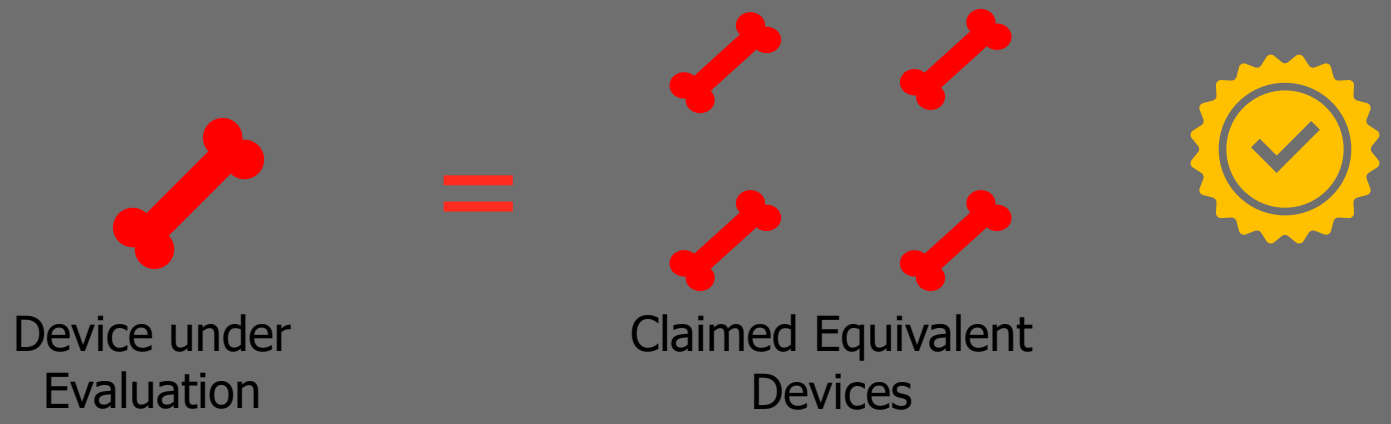
What are the general principles of Claiming Equivalence under the MDR?

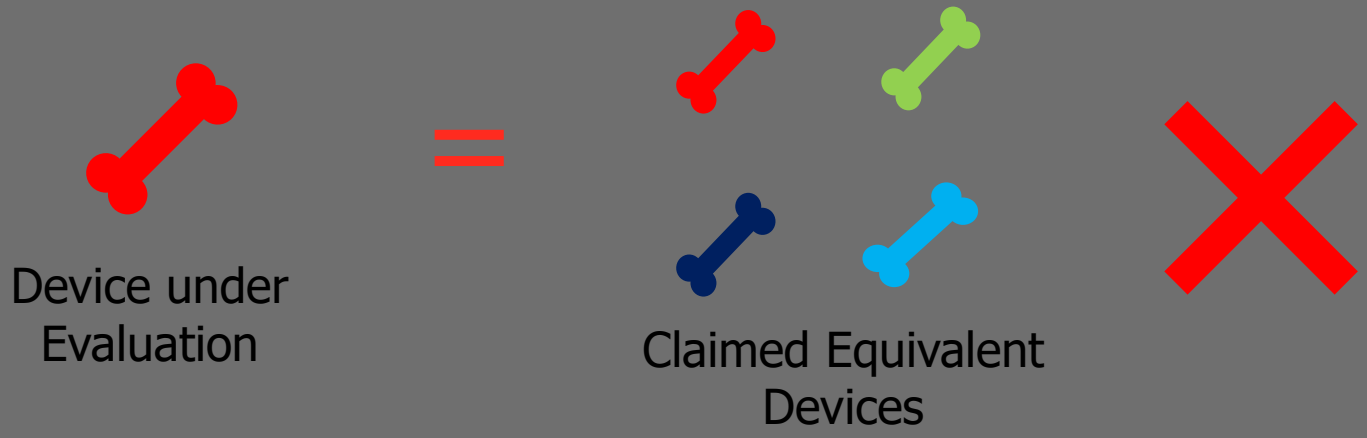
General Principles

Claiming Equivalence and Clinical Evaluation

- Equivalence does not exempt a device from having to perform a clinical evaluation.
- It is a requirement of the MDR to always perform a clinical evaluation.
- The process of claiming equivalence allows another device or devices clinical data to enter the clinical evaluation for assessment against the GSPRs

General Principles





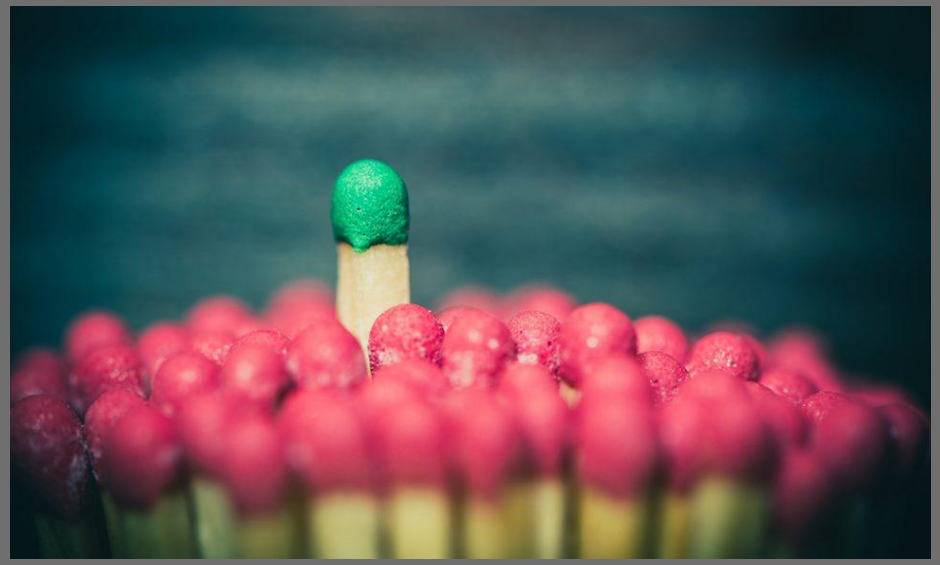
A device can claim equivalence to more than one device providing all biological, clinical and technical equivalence criteria can be achieved in all of the claimed equivalent devices.

Each claimed equivalent device must be fully investigated, described and demonstrated in the CER

It is not acceptable to use different parts of different devices to claim equivalence. (Sometimes referred to as the Frankenstein Approach)

General Principles

When there are some differences…



Pre-clinical data for the consideration of equivalence should allow a scientifically sound evaluation of technical and biological characteristics. Examples of data sources:

MDCG 2020-5 (4) (b)

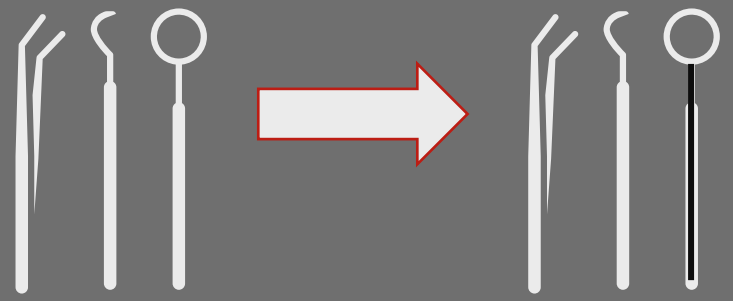
Any differences must be declared by the manufacturer and a scientific justification provided for the acceptability of no impact to performance or safety.

Biological and Technical Differences - may be supported by Pre-Clinical Data from the manufacturers own device or data published in the scientific literature (e.g. animal studies)

Any differences must demonstrate fully that there is no significant clinical impact to Safety or Performance - this assessment should be supported by clinical data, Common Specifications, Harmonised standards or Established Technical Specifications and duly justified.

This data must relate to the device under evaluation.

General Principles
Modifications



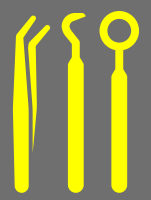
Modifications are permitted to claim equivalence. If the modifications are being introduced to address safety or performance concerns then the manufacturer should strongly justify that no **NEW** safety or performance concerns will be introduced (including those that are not associated with the existing issue).

Modifications to Class III and Implantable devices requires the manufacturer to perform PMCF and specifically post market studies for class III and implantable devices. (Article 61 (4))
Other devices should have some PMCF Activity planned to confirm S&P objectives/identify residual risk

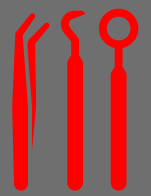
General Principles

Claiming Equivalence to a Previous Generation

Generation A – Clinical Data Obtained

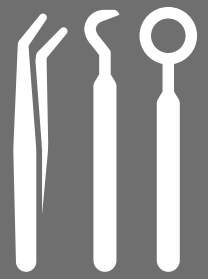


Generation B – No Clinical Data/Clinical Data Used from generation A



Generation C – No Clinical Data/Clinical Data Used from Generation A

Generation D



Device Under Evaluation (**Generation D**) is claiming Equivalence to **Generation C** but the clinical data relates to **Generation A.**

Pre-Clinical and Clinical data should be to a defined generation or version of a claimed equivalent device. (MDCG 2020-5 (4) (c))

When equivalence is claimed to a device that is reliant on clinical data from another previous generation, the manufacturer should strongly justify and demonstrate that the cumulative effects of any modifications or version upgrades have not been significant enough to impact safety or performance .

It should also be considered that any cumulative changes have not resulted in a device that is entirely different from the device that holds the clinical data, and therefore in this situation equivalence cannot be claimed.

In this scenario, consideration should also be given to 'state of the art' and whether the original clinical data obtained reflects current clinical practice or current technical capability.

IMDRF/GRRP WG/N47

A note of caution…

Opinion CECP-2021-000207

- *As the manufacturer presents several generations of the device, it is **not clearly specified which device generation has been used** in clinical trials, as is the need for generation changes. Importantly, one scientific report presents the fourth generation of the device, which follows the device under review.*
- *Clinical evidence related to the device in evaluation is mostly preclinical and robust regarding the product biocompatibility. There is no relevant clinical data, strong clinical data or expert recommendations regarding the device. No trials either ongoing or planned have been found related to the device. We conclude that the amount and quality of the clinical evidence supporting the device should be improved by the manufacturer.*

The Expert Panels have commented on an opinion indicating the need to specify which generations holds the clinical data on the device.

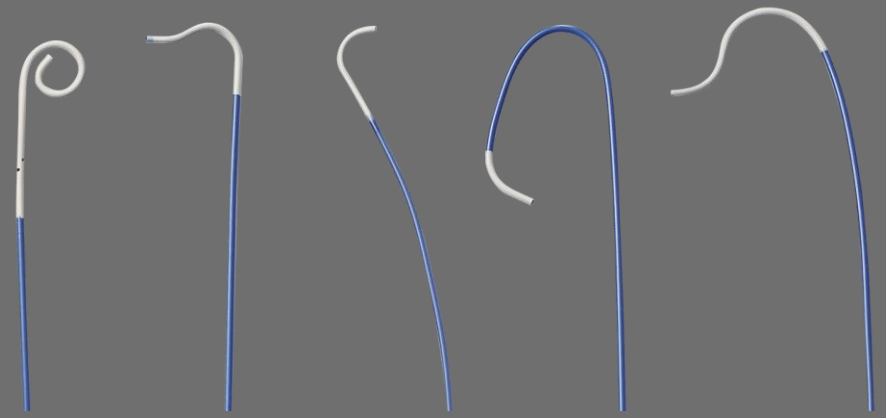
Poll Question

Can a manufacturer of a device claim equivalence with an ancillary medicinal substance to a device without an ancillary medicinal substance?

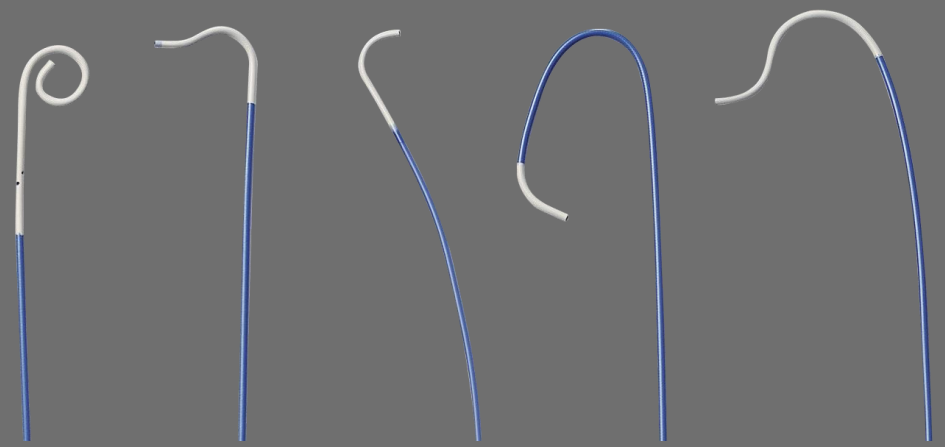
- Yes
- No

General Principles

Medicinal Substances & Equivalence



Heparin Coated Catheters

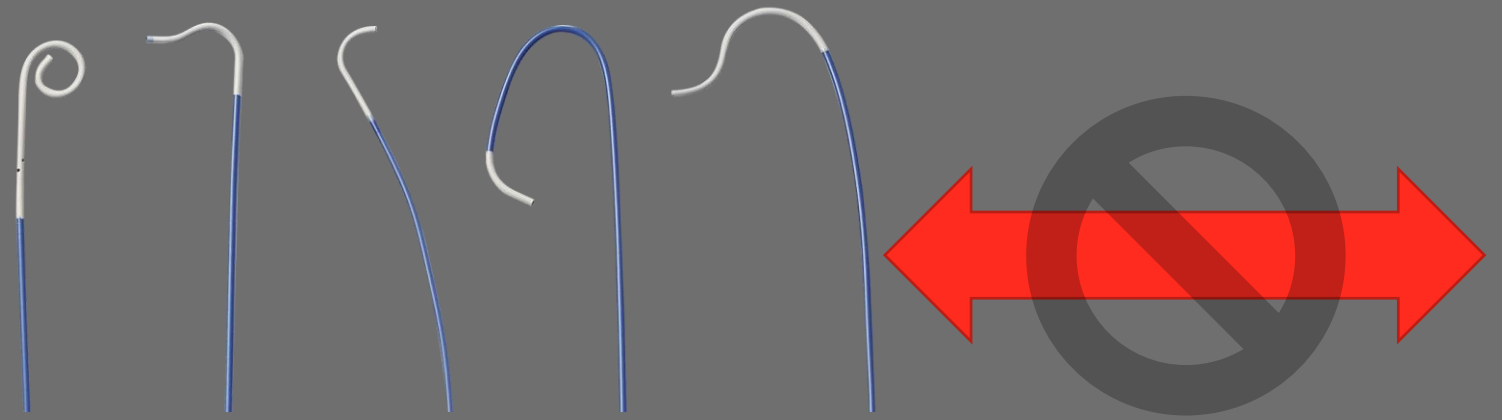


Non-Coated Catheters

Manufacturers cannot claim equivalence of a device with an ancillary medicinal substance to a device without an ancillary medicinal substance and vice versa.

General Principles

Medicinal Substances & Equivalence

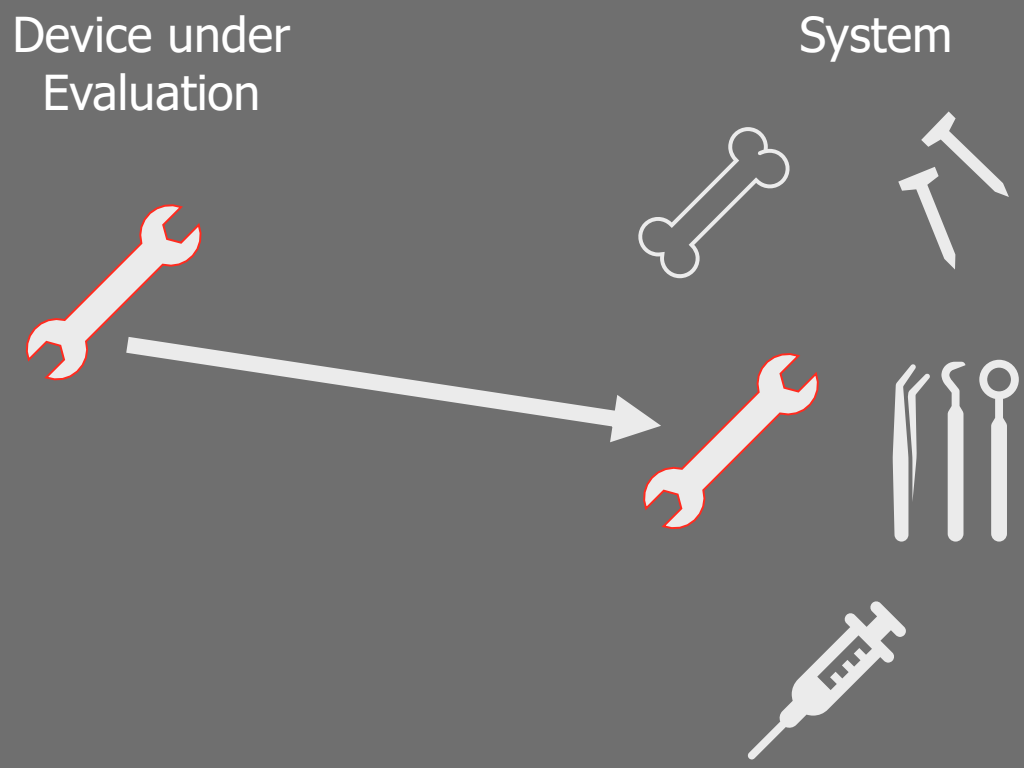


Heparin Coated Catheters

Manufacturers cannot claim equivalence of the ancillary medicinal substance to a ‘standalone’ medicinal substance.

General Principles

*Claiming Equivalence to a single or multiple devices within a system. *Exceptional Cases Only (*MDCG 2020-5)*

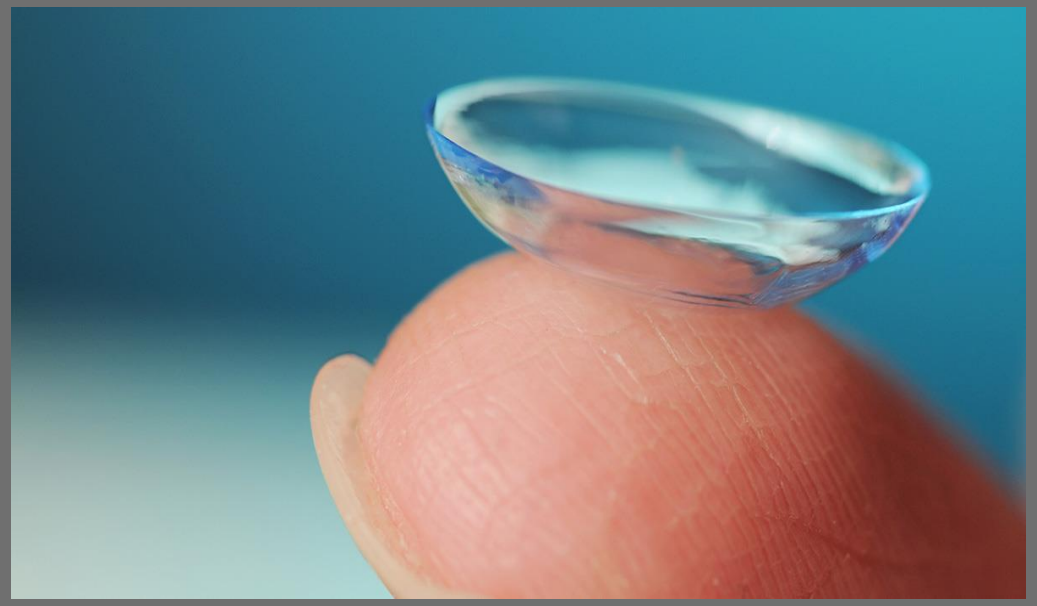


It is possible for a device to claim equivalence to a single device within a system providing;

- ✓ The system is manufactured by the same legal manufacturer
- ✓ Is 'currently marketed' (Explained later based on device classification)
- ✓ All three areas (biological, clinical and technical) must be successfully demonstrated per MDR Requirements
- ✓ The devices in the system do not impact the safety and performance of each other
- ✓ Potential interference on the device in the system and overall S&P of the device system shave been thoroughly investigated and documented.

* This principle should be considered for exceptional cases and should not be typically allowed for higher risk devices such as implantable devices.

Annex XVI Devices – Without an 'Intended Medical Purpose'



No

Yes*

A manufacturer of a medical device shall not claim equivalence to a product without an intended medical purpose listed in the MDR Annex XVI.

What are the requirements around claiming equivalence based on classification?

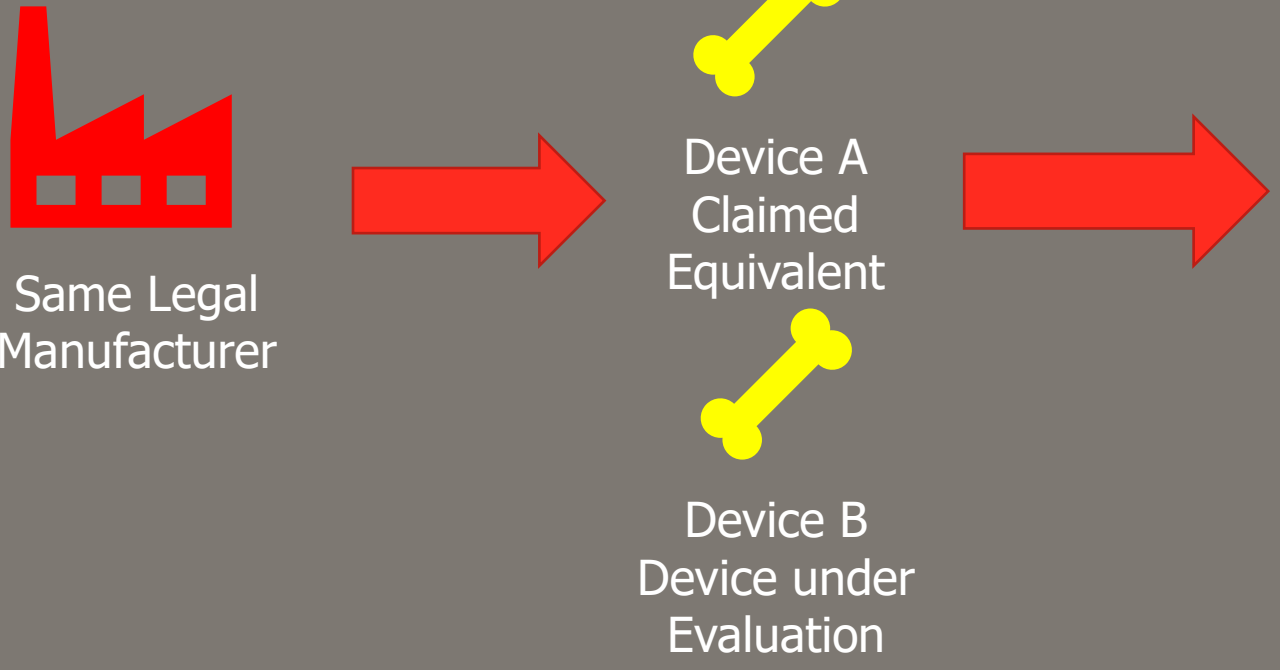
Poll Question

A manufacturer of a Class III device is claiming equivalence to their **own** device.

Can that device be certified under the MDD/AIMDD?

- Yes
- No

Class III and Implantable Devices - *Same Manufacturer*



For Equivalence to be claimed to a Class III and Implantable device of the same manufacturer the following conditions need to be met for the equivalent device ;

- *Valid CE Certificate to either MDD, AIMDD or MDR*
- *Clinical Evaluation should be up to date*
- *Benefit/Risk Ratio should be favourable*

Notes:
Clinical evaluation should be up to date- the NB may request a copy of the equivalent device CER to confirm it has been updated. If we (the NB) have reviewed the CER of the equivalent device recently i.e. within the manufacturers agreed update cycle, we may not need to request the CER and could make reference to this assessment.

We are not expected to re-assess the benefit/risk ratio of the equivalent device, however we should confirm the equivalent device has no newly identified safety concerns that could impact benefit/risk since its previous NB assessment.

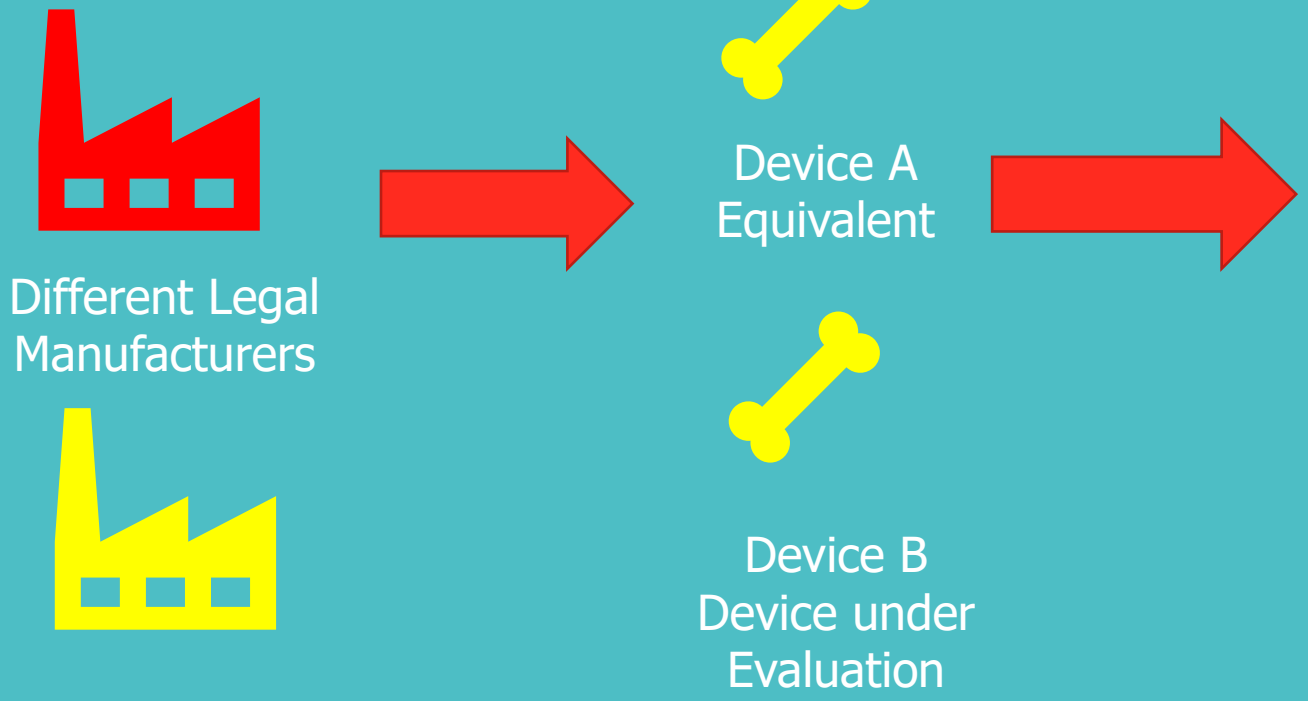
Poll Question

A manufacturer of a Class III device is claiming equivalence to another manufacturer's device.

Can that device be certified under the MDD/AIMDD?

- Yes
- No

Class III and Implantable Devices - *Different Manufacturer*



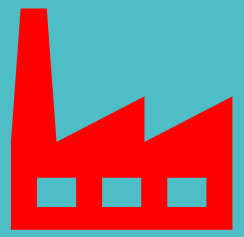
For Equivalence to be claimed to a Class III and Implantable device of a **different** manufacturer the following conditions need to be met for the equivalent device ;

- *Valid CE Certificate **to MDR Only***
- *Contract in place allowing **full access** to technical documentation.*
- *PMCF plan **includes** Post Market Studies (Article 61 (4))*

What is expected in the contract?

- Clear statement allowing **full and ongoing** access to technical documentation.
- Signed by both parties.
- Appropriately dated.

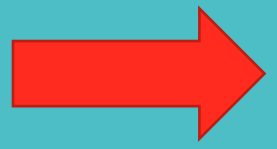
Class IIa/IIb Non–Implantable Devices

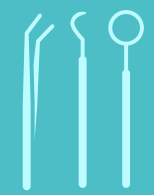


Same Legal Manufacturer

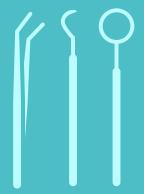
+/-

Different Manufacturers





Device A Equivalent



Device B Device under Evaluation

For Equivalence to be claimed to a Class IIa/IIb Non-implantable device the following conditions need to be met for the claimed equivalent device;

- *Claimed Equivalent **holds or has held** a MDD or MDR Certificate.*
- *The regulatory status of the claimed equivalent device should be disclosed.*

Notes:
The Claimed Equivalent Device could have been marketed outside of EU however the following criteria must be successfully demonstrated by the manufacturer

- *Sufficient Access to Data (Article 61 (3))*
- *Clinical Investigations were conducted to international guidance i.e. ISO14155*
- *Clinical data meets the requirements of MDR*
- *Justification that the data is transferrable to EU population*

Clinical Data relating to Equivalence.

sections 8-10 of MEDDEV 2.7/1 rev. 4.

In the event that the data do not meet the MDR definition of clinical data these are not clinical data and cannot be subject to data appraisal, analysis and evaluation for the purpose of providing clinical evidence for the confirmation of conformity with the relevant GSPR.

MDCG 2020-5 (Section 6)

1. Does the provided clinical data meet the definition of 'Clinical Data'? (Article 2(48))

2. Has all favourable and unfavourable data been provided for the equivalent **and** the device under assessment?

3. If the data meets the definition of clinical Data then Appraisal & Analysis

(48) 'clinical data' means information concerning safety or performance that is generated from the use of a device and is sourced from the following:

— clinical investigation(s) of the device concerned,

— clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated,

— reports published in peer reviewed scientific literature on other clinical experience of either the device in question or a device for which equivalence to the device in question can be demonstrated,

— clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up;

Data that does **NOT** meet those listed here **CANNOT** be used for claims of equivalence.

Poll Question

A manufacturer only requires a sufficient level of access to clinical data for Class III and Implantable.

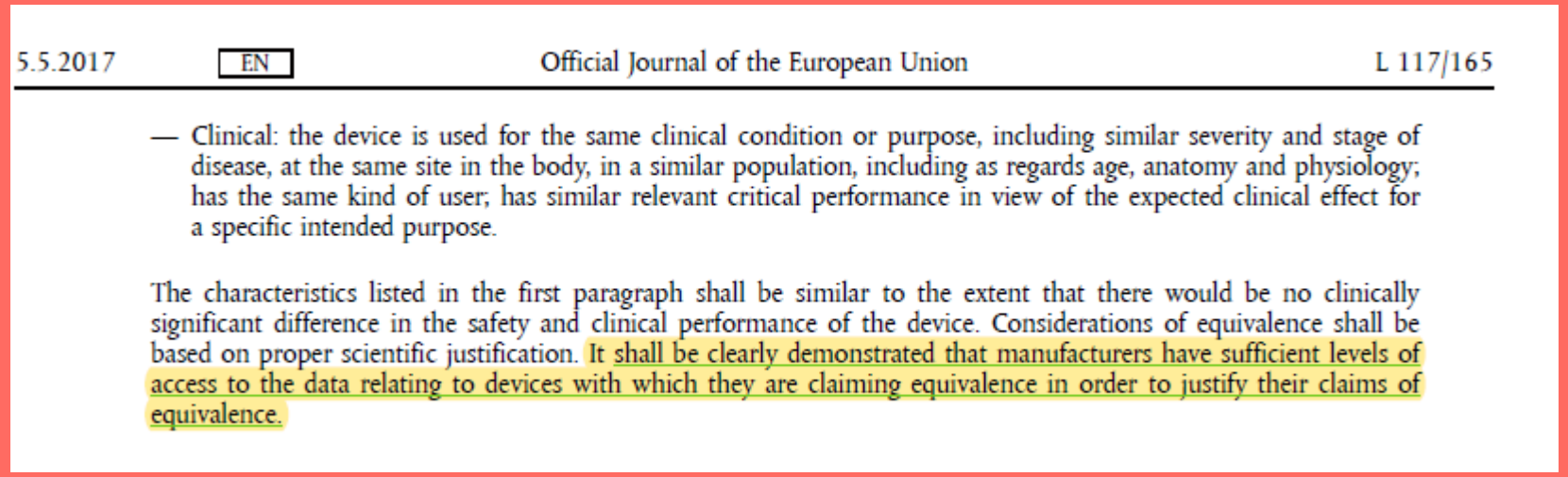
a. True

b. False

What is 'Sufficient' Access to data?

If a manufacturer is not able to demonstrate sufficient levels of access to the data[38] relating to the presumed equivalent device and needed for the consideration of equivalence, equivalence claims cannot be made for the purpose of conformity assessment. (MDCG 2020-5 Section 4 (c))

38 = MDR, Annex XIV Part A (3) last paragraph.



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— Clinical: the device is used for the same clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.

The characteristics listed in the first paragraph shall be similar to the extent that there would be no clinically significant difference in the safety and clinical performance of the device. Considerations of equivalence shall be based on proper scientific justification. It shall be clearly demonstrated that manufacturers have sufficient levels of access to the data relating to devices with which they are claiming equivalence in order to justify their claims of equivalence.

What is ‘Sufficient’ Access to data?

Class III & Implantable

Contract in Place for full access to technical documentation or Same Legal Manufacturer

All Other Devices

Sufficient access - *the manufacturer has adequate access to the clinical data and is able to demonstrate conformity to the GSPRs with the level of access they have.*

This also means that the manufacturer should be able to adequately answer any appropriate questions raised by the NB in relation to the data as part of the conformity to the GSPRs

Common issues which affect scientific validity of data generated – (Class IIa/IIb Non-implantable)

RCT and observational studies (literature)

- Publication bias
- Duplication bias
- Time lag bias
- Missing data (e.g. study conduct, deviations, reasons for LTFU)
- Little transparency of research methods and data analysis
- No access to raw data
- Flawed synthesis of data (meta-analyses)

(48) 'clinical data' means information concerning safety or performance that is generated from the use of a device and is sourced from the following:

— clinical investigation(s) of the device concerned,

— clinical investigation(s) or other studies reported in scientific literature, of a device for which equivalence to the device in question can be demonstrated,

— reports published in peer reviewed scientific literature on other clinical experience of either the device in question or a device for which equivalence to the device in question can be demonstrated,

— clinically relevant information coming from post-market surveillance, in particular the post-market clinical follow-up;

These factors should be considered particularly for Class IIa / IIb non-implantable devices claiming equivalence.

It should also be considered that whilst there is an acceptance that access to 'sufficient data' may have limitations for Class IIa & IIb non-implantable devices, there has to be acceptance that these sources are acceptable per Article 2 definition 48 'Clinical Data'

Similar Device Data

(7) 'generic device group' means a set of devices having the same or similar intended purposes or a commonality of technology allowing them to be classified in a generic manner not reflecting specific characteristics;

MDR (Article 2 (7))

Similar devices are **NOT** equivalent devices but the use of data from devices that share a same or similar intended purpose can provide value to the clinical evaluation of a device claiming equivalence.

Examples Include…

1. Identifying relevant risk or Hazards for the purpose of risk management
2. Understanding state of the art /alternatives
3. Identify design features that have safety or performance concerns
4. Provide input to CI or PMCF, PMS design.
5. Identify specific clinical outcomes
6. Help quantify acceptability of performance and risks

When can Similar data be used to support a conformity Assessment?

Medical Device

Medical Device Coordination Group Document MDCG 2020-6

MDCG 2020-6

Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC

A guide for manufacturers and notified bodies

April 2020

6	Evaluation of state of the art, including evaluation of clinical data from similar devices as defined in Section 1.2 of this document	This is not considered clinical data under the MDR, but for well-established technologies only can be considered supportive of confirmation of conformity to the relevant GSPRs. Data from similar devices may be also important to establish whether the device under evaluation and similar devices belong to the group of devices considered as "well established technologies" (WET). See section 1.2 in this document for the criteria for WET. Data from similar devices may be used, for example, to demonstrate ubiquity of design, lack of novelty, known safety and performance profile of a generic group of devices, etc.

Whilst similar data does not meet the definition of 'Clinical Data' per article 2 (48), there is allowance for WET to use this data to support confirmation of conformity relevant GSPRs.

Annex XVI Devices

An analogous device, in this context, is understood as a medical device which is similar in terms of functioning and risks profile and has a medical purpose[44].

44= MDR, Recital (12).

- Annex XVI devices should perform clinical investigations.
- Allowance for reliance of existing clinical data from an 'Analogous Medical Device'
- Principle demonstrations of Equivalence still required but taking into account the claimed equivalent device will have an aesthetic of non-medical purpose
- *The general requirement to demonstrate a clinical benefit shall be understood as a requirement to demonstrate the performance of the device.*
- Common Specifications (for Annex XVI device) regarding safety should also be considered with impact of any differences/deviations identified and must conclude there are no clinical differences in safety.

Technical, Biological and Clinical
Same or Similar?

The Terms "Same & Similar"

Same = of an identical type; ***exactly similar….***

Similar = having a resemblance in appearance, character, or quantity, without being identical…..

Oxford English Dictionary

…..and that there would be no clinically significant difference in the safety and clinical performance of the device.

MDCG 2020-5

Technical Equivalence

— Technical: the device is of similar design; is used under similar conditions of use; has similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software algorithms; uses similar deployment methods, where relevant; has similar principles of operation and critical performance requirements;

MDR Annex XIV (3)

- Similar Design
- Similar conditions of use
- Similar specifications and properties
- Similar deployment methods
- Similar principles of operation and critical performance

MDCG 2020-5: Clinical Evaluation - Equivalence

Differences between MedDev 2.7/1 and MDR equivalence criteria

Technical:

MedDev 2.7/1

"used under **same** conditions"

MDR

"used under **similar** conditions"

The conditions of use shall be similar to the extent that there would be no clinically significant difference in the safety and clinical performance

MDCG 2020-5: Clinical Evaluation - Equivalence

Differences between MedDev 2.7/1 and MDR equivalence criteria

Technical:

MedDev 2.7/1

"have similar specifications and properties (e.g. physicochemical properties such as type and intensity of energy, tensile strength, viscosity, surface characteristics, wavelength, surface texture, porosity, particle size, nanotechnology, specific mass, atomic inclusions such as nitrocarburising, oxidability),"

MDR

"has similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software algorithms;"

Why are the examples different?
They are examples only and must not be interpreted as an exhaustive list of specifications and properties of technical characteristics when considering equivalence to another device.

MDCG 2020-5: Clinical Evaluation - Equivalence

Differences between MedDev 2.7/1 and MDR equivalence criteria

Technical:

MedDev 2.7/1

"have similar specifications and properties (e.g. physicochemical properties such as type and intensity of energy, tensile strength, viscosity, surface characteristics, wavelength, surface texture, porosity, particle size, nanotechnology, specific mass, atomic inclusions such as nitrocarburising, oxidability),"

MDR

"has similar specifications and properties including physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software algorithms;"

Software algorithms are specifically called out:

- includes software algorithms which drive or influence the use of a device, and standalone software
- Intention is to demonstrate equivalence of functional principles, clinical performances and intended purpose, not similarity of code
- Presumption is that software is developed in line with international standards for safe design and validation of medical device software (eg IEC 62304 and IEC 82304-1)
- Software intended solely for device configuration (e.g. graphical user interface) does not need to be similar as long as there is no negative impact on usability, safety or performance

Biological Equivalence

— Biological: the device uses the same materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables;

MDR Annex XIV (3)

- Same Material or Substances
- Same Human Tissues or Body Fluids
- Similar Kind and duration
- Similar release characteristics

MDCG 2020-5: Clinical Evaluation - Equivalence

Differences between MedDev 2.7/1 and MDR equivalence criteria

Biological:

MedDev 2.7/1

"Exceptions can be foreseen for devices in contact with intact skin and minor components of devices; in these cases risk analysis results may allow the use of similar materials taking into account the role and nature of the similar material."

MDR

~~"Exceptions can be foreseen for devices in contact with intact skin and minor components of devices; in these cases risk analysis results may allow the use of similar materials taking into account the role and nature of the similar material."~~

- The exception for devices in contact with intact skin and "minor components" is removed – if it comes into contact with human tissues, the materials **must be the same***.
- The wording still allows for differences in materials that do not come into contact with human tissues, providing the differences do not affect the device technical characteristics

MDCG 2020-5: Clinical Evaluation - Equivalence

Differences between MedDev 2.7/1 and MDR equivalence criteria

Biological:

MedDev 2.7/1

"Use the same materials or substances in contact with the same human tissues or body fluids."

MDR

"The device uses the same materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables."

How can "the same" materials have only "similar" release characteristics and substances?

- The distinction is made to account for the fact that processing, design and the use environment may introduce small changes even when the raw materials are the same – for example, small changes in pH or oxidative stress can increase or decrease release characteristics, but these materials could still be considered the "same" under the MDR, providing the difference is not considered to have a negative impact on safety and performance.

MDCG 2020-5: Clinical Evaluation - Equivalence

Differences between MedDev 2.7/1 and MDR equivalence criteria

Biological:

MedDev 2.7/1

"Use the same materials or substances in contact with the same human tissues or body fluids."

MDR

"The device uses the same materials or substances in contact with the same human tissues or body fluids for a similar kind and duration of contact and similar release characteristics of substances, including degradation products and leachables."

Note 1:

- The guidance and the MDR Annex XIV Part A both say that clinical, technical and biological criteria "**shall be taken into consideration**". This specific language was debated extensively in the working group and its use is deliberate. The intention is that the word "shall" applies to the consideration, rather than to the criteria itself. This allows some risk-based interpretation of the impact of differences in any of these three criteria.

Clinical Equivalence

— Clinical: the device is used for the same clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology; has the same kind of user; has similar relevant critical performance in view of the expected clinical effect for a specific intended purpose.

MDR Annex XIV (3)

- Same Clinical Condition or Purpose
- Similar severity and stage of disease
- Same site in the body anatomical location
- Similar population
- Same User
- Similar clinical effect

MDCG 2020-5: Clinical Evaluation - Equivalence

Differences between MedDev 2.7/1 and MDR equivalence criteria

Clinical:

MedDev 2.7/1

"- used for the same clinical condition (including when applicable similar severity and stage of disease, same medical indication), and

- used for the same intended purpose, and

- used at the same site in the body, and

- used in a similar population (this may relate to age, gender, anatomy, physiology, possibly other aspects),"

MDR

"The device is used for the same clinical condition or purpose, including similar severity and stage of disease, at the same site in the body, in a similar population, including as regards age, anatomy and physiology"

- Removal of reference to same medical indication, gender and duration of use is not intended to mean that these parameters need not be considered – the difference reflects the fact that the authors considered these parameters to already be contained within the requirement for "same clinical condition or purpose"
- "This is supported by the definitions in the MDR of the 'intended purpose', and the ability of the device to achieve its intended purpose by the 'clinical performance' including measurable 'clinical benefit'."

MDCG 2020-5: Clinical Evaluation - Equivalence

Differences between MedDev 2.7/1 and MDR equivalence criteria

Clinical: **MedDev 2.7/1**

MDR

"has the same kind of user"

- The MDR now specifically requires a consideration of whether the user's competence (eg lay person vs healthcare professional) can have an impact on the safety, performance or clinical outcomes of the device.
- This is consistent with the technical "conditions of use" criteria, which would mean that (for example) a device intended for home use may not be considered to be equivalent to one intended for use in a healthcare setting.

Documenting Equivalence in the CER.

- ✓ Clearly identify the equivalent device(s).
- ✓ Use the table in Annex I of MDCG 2020-5
- ✓ Identify the differences
- ✓ Provide a Scientific Justification

BSI Medical Devices – Use Our Resources

https://www.bsigroup.com/en-GB/medical-devices/resources

Brochures, Guides and Documents

MDR guidance

MDD Best Practice Guidelines >
MDR Best Practice Guidelines >
MDR Mapping Guide >
MedDev 2.7.1 Rev 4 changes >
MDR Conformity Routes >
MDR Readiness Review >

Webinars

MDR Conformity Assessment Routes webinar

MDR - What we know

Download the presentation >

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Share your knowledge, challenges and news with others on LinkedIn.

White Papers and Articles

Person responsible for regulatory compliance (PRRC) - MDR/IVDR Article 15

With the MDR and IVDR, European regulators aim to ensure companies have a regulatory expert – a Person Responsible for Regulatory Compliance (PRRC) – at their disposal, to ensure that the company is meeting certain specific EU requirements.

Software as a medical device - A comparison of the EU's approach with the US's approach

The International Medical Device Regulators Forum (IMDRF) aims to accelerate international medical device regulatory convergence. Through the IMDRF, regulators reached consensus on what software is considered a medical device. Regulators call it 'software as a medical device' (SaMD). This paper provides a comparison of how SaMD is regulated in the US and in the EU.

Machine learning AI in medical devices

How is AI different from traditional medical devices and medical software and what are the implications of those differences? What controls are necessary to ensure AI in healthcare is safe and effective?

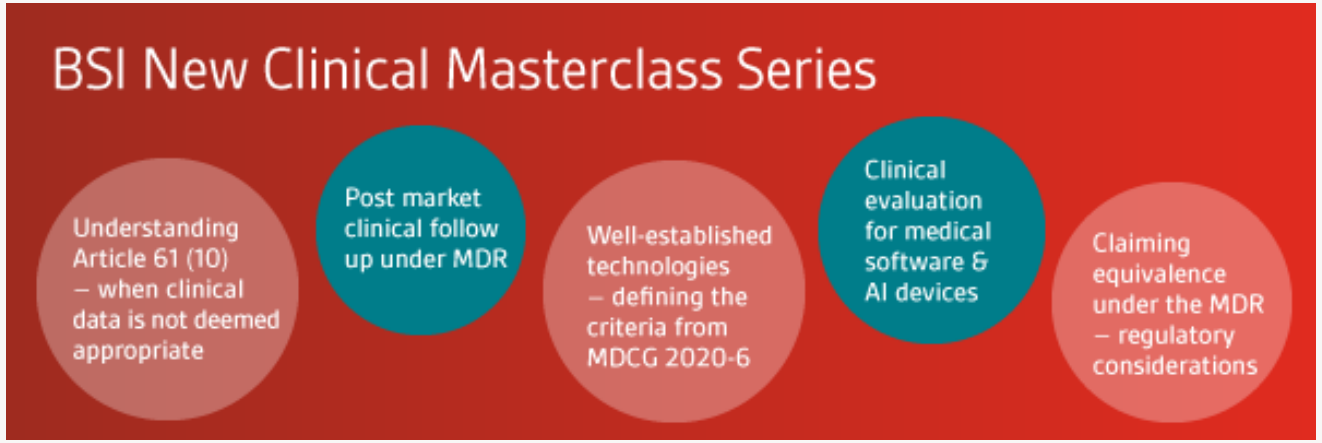
Medical device clinical investigations – What's new under the MDR?

The conduct of a clinical investigation is one of the most time consuming and resource intensive activities that a medical device manufacturer can face. This paper discusses important new requirements for pre-market and post-market clinical investigations under the European MDR.

Training Resources

Medical devices regulation (MDR)	
Transition from MDD to MDR	1 day
Technical Documentation for CE - Marking	1 day
Requirements of MDR for CE - Marking	1 day
Implementing of MDR for CE- Marking	3 days

Further courses for medical devices manifacturers	
Medical Device Single Audit Program (MDSAP)	2 days
ISO 14971 Risk Management	1 day
Creating and Maintaining Technical Files	1 day
Post-market Surveillance and Vigilance	1 day
Clinical Evaluation for Medical Devices	1 day
Process Validation for the Medical Device Industry	1 day
Introduction to Medical Device Software	1 day



We have more webinars available in our Clinical Masterclass series.

The next webinar available is:

2nd March 2022 – Clinical Evaluation for Medical Software & AI Devices

Use the link to sign up to this webinar and any other webinar(s) in the series:

https://www.bsigroup.com/en-GB/medical-devices/resources/webinars/2022/mdr/clinical-masterclass/

Questions

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