MDCG 2020-5

Clinical Evaluation - Equivalence

A guide for manufacturers and notified bodies

April 2020

This document has been endorsed by the Medical Device Coordination Group (MDCG) established by Article 103 of Regulation (EU) 2017/745. The MDCG is composed of representatives of all Member States and it is chaired by a representative of the European Commission.The document is not a European Commission document and it cannot be regarded as reflecting the official position of the European Commission. Any views expressed in this document are not legally binding and only the Court of Justice of the European Union can give binding interpretations of Union law.

Clinical Evaluation - Equivalence
A guide for manufacturers and notified bodies

1 Table of contents

1. Introduction 4
2. Scope 5
3. Equivalence 5
   3.1 Technical characteristics 5
   3.2 Biological characteristics 6
   3.3 Clinical characteristics 9
4. Demonstration of equivalence 10
5. Use of data from similar devices 14
6. Clinical data identification 15

Annex I – Equivalence table 16

1. Introduction

This guidance document is not legally binding. It has been put together following contribution from national competent authorities, industry and relevant stakeholders and it should therefore be recognised as best practice.

The Regulation (EU) 2017/745 on medical devices[1], hereafter referred to as the MDR (medical device regulation), provides a possibility to use clinical data related to an equivalent device in the clinical evaluation required for a device under conformity assessment[2].

Whilst carrying out a clinical investigation is the most direct way to generate clinical data concerning the safety and performance of medical devices for the purpose of CE marking, clinical data can also be sourced from[3]

- *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*

Equivalence shall be demonstrated according to the MDR requirements[4].

The European Commission has published a guide on clinical evaluation under the directives 93/42/EEC and 90/385/EEC; MEDDEV 2.7/1 rev. 4[5]. This MEDDEV guide should be used also during the process of demonstrating equivalence under the MDR. However, it has been recognised that some of the requirements set out in MEDDEV 2.7/1 rev. 4 are not fully aligned with the MDR and that further guidance to address the differences would be of benefit to industry and other stakeholders. Only the text of the MDR is legally binding. In cases of divergence between the MEDDEV 2.7/1 rev. 4, this MDCG guidance and the MDR, the MDR shall take precedence.

This MDCG guidance does not introduce any new requirements.

The demonstration of equivalence does not remove the requirement to always conduct a clinical evaluation in accordance with the MDR. It is the demonstration of equivalence[6] that allows the manufacturer to let clinical data from an equivalent device enter the clinical evaluation process of the device in question for the purpose of confirmation of conformity with relevant general safety and performance

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2017:117:TOC

[2] MDR, Article 61 and Annex XIV Part A.

[3] MDR, Article 2 (48) 2nd and 3rd indent.

[4] MDR, Annex XIV, Part A (3).

[5] MEDDEV 2.7/1 revision 4, Guidelines on medical devices, clinical evaluation: A guide for manufacturers and notified bodies under directives 93/42/EEC and 90/385/EEC https://ec.europa.eu/growth/sectors/medical-devices/current-directives/guidance_en

[6] MDR, Annex XIV, Part A (3).

requirements[7]. There may also be other sources of clinical data than from an equivalent device[8] to include in the process of clinical evaluation.

2. Scope

This MDCG guidance covers the demonstration of equivalence, based on data pertaining to an already existing device on the market[9], for the purpose of CE-marking under the MDR.

One of the purposes of this document is to highlight the differences between the MDR and the MEDDEV 2.7/1 rev.4 specifically with regards to equivalence. It is also intended to provide additional guidance and support a harmonised approach to the demonstration of equivalence across the EU.

In addition, non-exhaustive guidance and references have been provided with respect to device considerations for medical devices incorporating an ancillary medicinal product.

This MDCG guidance also covers products without an intended medical purpose listed in Annex XVI of the MDR.

3. Equivalence

The MDR requires[10] that technical, biological and clinical characteristics are considered when demonstrating equivalence to another device. Whilst these general characteristics are described in the MEDDEV 2.7/1 rev. 4 Appendix 1 and are aligned with the MDR requirement, there are differences in the criteria that are set out for each of the three characteristics. Differences in criteria between the MDR and the MEDDEV 2.7/1 rev. 4 are highlighted below and are accompanied by some explanatory text.

3.1 Technical characteristics

MDR, Annex XIV Part A (3)	MEDDEV 2.7/1 rev 4, Appendix A1
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.	- be of similar design, and - **used under the same conditions of use,** and - 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), and - use similar deployment methods (if relevant), and - have similar principles of operation and critical performance requirements

[7] MDR, Article 61 (1) and (3 (a)).
[8] MDR, Article 2 (48) 1st and 4th indent.
[9] Whether the 'market' is presumed to be the EU market or not is related to requirements in Article 61. See section 4 (d) and (e) in this document for further guidance.
[10] MDR, Annex XIV Part A (3).

(a) The MDR requires that technical characteristics shall be taken into consideration for the demonstration of equivalence including that the device in question and the device presumed to be equivalent are "used under **similar conditions** of use". MEDDEV 2.7/1 rev. 4, however, specifies use under the **same** conditions with regard to technical characteristics[11]. The conditions of use shall be similar to the extent that there would be no clinically significant difference in the safety and clinical performance between the device in question and the device presumed to be equivalent. For further guidance on the assessment of 'similar', see also section 4 of this document.

(b) Different examples are given for specifications and properties of the device when considering technical characteristics across the two definitions. These are examples only and are to be considered as such. They must not be interpreted as an exhaustive list of specifications and properties of technical characteristics when considering equivalence to another device. Note however that the MDR specifically points out that **software algorithms** shall be similar in the device presumed to be equivalent. This includes software algorithms in software driving or influencing the use of a device, and in software intended to be used alone[12]. It is the functional principle of the software algorithm, as well as the clinical performance(s) and intended purpose(s) of the software algorithm, that shall be considered when demonstrating the equivalence of a software algorithm. It is not reasonable to demand that equivalence is demonstrated for the software code, provided it has been developed in line with international standards for safe design and validation[13] of medical device software.

Software solely intended for the configuration of a device (e.g. presentation on a graphical user interface etc), and not related to any medical purpose[14] (e.g. diagnosis, treatment etc), does not need to be similar when considering equivalence as long as it can be justified to not negatively affect the usability, safety or clinical performance.

3.2 Biological characteristics

MDR, Annex XIV Part A (3)	MEDDEV 2.7/1 rev. 4, Appendix A1
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**	Use the same materials or substances in contact with the same human tissues or body fluids. **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.

[11] "Conditions of use" with regard to technical characteristics may e.g. be environmental factors such as magnetic fields, temperature, moisture, conditions during transport of device in use etc.
See section 3.3 in this document regarding use for the same clinical condition or purpose.
[12] See MDCG 2019-11 Guidance on Qualification and Classification of Software in Regulation (EU) 2017/745 - MDR and Regulation (EU) 2017/746 – IVDR.
[13] E.g. IEC 62304 Medical device software – Software life cycle processes, and IEC 82304-1 Health software – Part 1: General requirements for product safety.
[14] MDR, Article 2(1).

(a) Manufacturers must consider the additional text in the MDR and adequately specify all applicable characteristics. The exceptions, outlined in the MEDDEV 2.7/1 rev 4, to not use the same materials are NOT acceptable under the MDR.

The MDR requires that biological characteristics shall be taken into consideration for the demonstration of equivalence, i.e. 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 with similar release characteristics of substances, including degradation products and leachables, as the presumed equivalent device. The distinction between "same materials or substances" and "similar release characteristics of substances" 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.

Processing can make materials more susceptible to degradation by changing properties of the material and/or by inducing different stresses. For example, small changes in pH or oxidative stress can increase or decrease release characteristics. For this reason, it is the final device that shall be assessed.

(b) The principles outlined in ISO 10993 series of standards for the biological evaluation of medical devices can be adopted, in particular the ISO 10993-1 for a risk-based approach to biological evaluation[15] and also for material characterization.

In addition, the ISO 10993-18 which covers chemical characterization of materials can be adopted to specify the identity of materials and to estimate the type and quantity of leachables from the final device. Annex C of this standard addresses biological equivalence. The ISO 10993-17 includes principles on the toxicological risk assessment of leachables. Leachables may include degradation products or other substances from the materials or substances that the device is made of, but also other constituents for example residuals from the manufacturing process or sterilisation, any contaminations etc. Therefore, for the consideration of equivalence, it is the properties and characteristics of the final device that shall be taken into account.

For degradable materials, ISO 10993, Parts 13, 14 and 15 address the identification and quantification of degradation products. Note, that there may be further parts in the ISO 10993 series of standards that are relevant for the device in question.

(c) The MDR has additional requirements[16] for **devices that are composed of substances or of combinations of substances** that are intended to be introduced into the human body, and that are absorbed by or locally dispersed

[15] ISO 10993-1 Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process, and collateral standards in the 10993 series.
[16] MDR, Annex I, (12.2).

in the human body. For the consideration of equivalence, the substances shall be the same.

Those devices are not medicinal products, but for the conformity assessment they shall comply with the relevant requirements laid down in Annex I to Directive 2001/83/EC[17] for the evaluation of absorption, distribution, metabolism, excretion, local tolerance, toxicity, interaction with other devices, medicinal products or other substances and potential for adverse reactions. This means that for the demonstration of equivalence under the MDR, those aspects shall also be taken into consideration.

Note that the requirement[18] that the notified body shall seek a scientific opinion from a competent authority for medicinal products or the EMA, for the device or its products of metabolism, that are systemically absorbed by the human body in order to achieve their intended purpose, on the compliance with the relevant requirements laid down in Annex I to Directive 2001/83/EC, always applies for the device under evaluation even if equivalence has been demonstrated under the MDR.

(d) The demonstration of equivalence may also concern **medical devices with an ancillary medicinal substance**, for example drug-eluting stents or heparin-bonded central venous catheters.

The MDR requires[19] that biological characteristics shall be taken into consideration for the demonstration of equivalence, including that the device in question and the device presumed to be equivalent, use “the same materials or substances in contact with the same human tissues or body fluids”. This applies also to the medicinal substance and any related excipients/coatings.

Excipients/coatings may potentially have a significant effect for example on the release characteristics of the medicinal substance intended only for a local effect from a stent, and thereby a significant effect on the clinical performance.

In all cases, concerning the device under evaluation, the notified body shall[20]

- verify the usefulness of the substance as part of the device, taking account of the intended purpose of the device, and
- seek a scientific opinion from a competent authority for medicinal products or the EMA to ensure that the quality, safety and benefit/risk of using the ancillary medicinal product, including whether the manufacturing process have been adequately assessed.

[17] Directive 2001/83/EC relating to medicinal products for human use.
[18] MDR, Annex IX, Chapter II, 5.4 (b).
[19] MDR, Annex XIV Part A (3) second indent.
[20] MDR, Annex IX, Chapter II, 5.2. (b) and (c).

Note that medical devices with an ancillary medicinal substance are class III devices[21]. In cases where a manufacturer intends to claim equivalence to a device not manufactured by him, the MDR requires that 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[22] .

Manufacturers cannot claim equivalence of a device with an ancillary medicinal substance to a device without an ancillary medicinal substance and vice versa. For example, the manufacturer of a heparin coated catheter shall not claim equivalence to a drug-free catheter even if both catheters are otherwise identical[23] . See also section 4 of this document.

Similarly, manufacturers shall not claim equivalence of the ancillary medicinal substance to a 'standalone' medicinal substance.

3.3 Clinical characteristics

MDR, Annex XIV Part A (3)	MEDDEV 2.7/1 rev. 4, Appendix A1
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.	- 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), and - not foreseen to deliver significantly different performances (in the relevant critical performances such as the expected clinical effect, the specific intended purpose, the **duration of use**, etc.)

(a) The MDR additionally requires that, for manufacturers to compare clinical characteristics, the device shall have the **same kind of user**. The MDR clearly points out that a user means any healthcare professional or lay person who uses a device[24], and that a lay person means an individual who does not have formal education in a relevant field of healthcare or medical discipline[25]. Manufacturers must therefore take into consideration whether the intended user's competence or knowledge can have any implication for the safety, clinical performance and outcome when considering equivalence between the device in question and the presumed equivalent device. For example, a device intended for professional use and a device intended for home use, but for the same clinical condition or purpose, may have a different safety and performance profile due to the environment in which they are intended to be used.

[21] MDR, Annex VIII, Rule 14.
[22] MDR, Article 61 (5).
[23] MDR, Annex XIV Part A (3).
[24] MDR, Article 2 (37).
[25] MDR, Article 2 (38).

(b) The MDR does not explicitly state that the medical device needs to be used for the **same medical indication, gender and duration of use** as the equivalent device. However, it is understood that in general, this is covered by the MDR requirement that both devices should be used for the **same clinical condition or purpose** including similar severity and stage of disease and also have similar relevant critical performance which is also outlined in the MEDDEV 2.7/1 rev. 4. This is supported by the definitions in the MDR of the 'intended purpose'[26], and the ability of the device to achieve its intended purpose by the 'clinical performance'[27] including measurable 'clinical benefit'[28].

4. Demonstration of equivalence

MDR, Annex XIV Part A (3)	MEDDEV 2.7/1 rev. 4, Appendix A1
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**.	For assuming equivalence, - all three characteristics (clinical, technical, biological) need to be fulfilled; - similar means that no clinically significant difference in the performance and safety of the device would be triggered by the differences between the device under evaluation and the device presumed to be equivalent.

There are a number of prerequisites that shall be fulfilled for the demonstration of equivalence:

(a) The overall considerations of equivalence shall conclude whether the listed technical, biological and clinical characteristics in the MDR[29] are similar to the extent that there would be no clinically significant difference in the safety and clinical performance of the device. Note that some of the listed characteristics in the MDR shall be the same, not only similar. The corresponding wording from MEDDEV 2.7/1 rev. 4 is presented for information above. Consideration must be given to the characteristics mentioned above and a gap analysis should be conducted by the manufacturer to evaluate any clinically significant difference(s).
Modifications[30] of a device may be implemented for a variety of reasons. If the differences have been introduced to address specific safety and/or performance issues it shall be duly justified, that there would be no clinically significant difference in the safety and clinical performance other than the intended improvements related to the specific issue that triggered the modification / difference. For all modifications and concomitant claims of equivalence, there must be no additional risks or potential of negatively altered performance related to the introduced modifications.

[26] MDR, Article 2 (12).
[27] MDR, Article 2 (52).
[28] MDR, Article 2 (53).
[29] MDR, Annex XIV Part A (3).
[30] MDR, Article 61 (4).

See a template example of an Equivalence table in the Annex I of this document.

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

(b) Manufacturers may identify more than one equivalent device to the device under evaluation, but each device shall be equivalent to the device under evaluation in all the listed technical, biological and clinical characteristics[31]. Equivalence to each device shall be fully investigated, described and demonstrated in the clinical evaluation report.
This means that manufacturers shall not use different parts of different devices to claim equivalence to the device under evaluation. The MEDDEV 2.7/1 rev. 4 is in line with this approach.
In exceptional cases, a deviation from this principle may be considered. There may be device systems comprised of several more or less "stand alone" devices, where it may be justified to consider equivalence of a device in the system to a presumed equivalent device in a device system already on the market (by the same manufacturer) provided that all technical, biological and clinical characteristics are same/similar[32], and that the devices in the system do not affect the safety and performance of each other. This should be duly investigated and documented both on the level of potential interference between the devices in the system, as well as on the overall safety and clinical performance of the device system.

(c) Regarding the clinical evaluation, the MDR requires[33] that the manufacturer shall specify and justify the level of clinical evidence necessary to demonstrate conformity with the relevant general safety and performance requirements. That level of clinical evidence shall be appropriate in view of the characteristics of the device and its intended purpose[34]. In addition, considerations of equivalence **shall be based on proper scientific justification**[35].

This implies that technical, biological and clinical characteristics shall be duly investigated and documented. The manufacturer is expected to fully identify and disclose any differences between the two devices.

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

---

[31] MDR, Annex XIV Part A (3), the requirement refers to only "a device" and "the device".
[32] MDR, Annex XIV Part A (3).
[33] MDR, Article 61 (1) second paragraph.
[34] MDR, Article 61 (1) second paragraph
It may under certain circumstances be justified to demonstrate conformity without support of clinical data, see MDR, Article 61 (10), but note that this is not applicable for implantable devices or class III devices.
[35] MDR, Annex XIV Part A (3)
For guidance see also MEDDEV 2.7/1 rev 4, Annex A6, Appraisal of clinical data - examples of studies that lack scientific validity for demonstration of adequate clinical performance and/or clinical safety.

- data from the technical documentation of a manufacturer's own presumed equivalent device (specifications, test-results, chemical/physical/biological analyses, data from pre-clinical investigations etc)
- data published in the scientific literature, e.g. animal or other pre-clinical data

The assessment of whether any differences in characteristics would result in clinically significant difference in safety and clinical performance shall also be duly substantiated and based on proper scientific justification. This assessment may be supported by e.g. clinical data from the scientific literature, common specifications (CS)[36], harmonised standards or other established technical specifications.
Furthermore, for the assessment of safety, a risk-based approach[37] is expected, both for the identification of characteristics that may affect safety as well as for the final assessment of equivalence regarding safety.

It is important for the consideration of equivalence that pre-clinical data and any clinical data relate to the actual device under evaluation, and to a defined generation/version of the actual device considered for equivalence, bearing in mind that there may be significant differences between different generations of the other device.

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.

(d) The MDR notes specific requirements in addition to the demonstration of equivalence in order not to perform a clinical investigation which must be taken into account.

A manufacturer of **implantable devices and class III devices** shall perform clinical investigations except if the device has been designed by modifications of a device already marketed by the **same manufacturer** and equivalence can be demonstrated according to the MDR[39]. In this context, a marketed device is considered to be a device already placed on the market and CE marked with respect to either the MDR or the directives 93/42/EEC or 90/385/EEC. The CE marking should still be valid, should be based on an updated clinical evaluation, and the benefit/risk ratio for this device should be favourable.

[36] MDR, Article 2, (71) 'common specifications' (CS) means a set of technical and/or clinical requirements, other than a standard, that provides a means of complying with the legal obligations applicable to a device, process or system.
[37] ISO 14971 Medical devices – Application of risk management to medical devices, and also other related standards as applicable e.g. ISO 10993-1 and ISO 10993-18.
[38] MDR, Annex XIV Part A (3) last paragraph.
[39] MDR, Article 61 (4), and Annex XIV (3).

For a manufacturer of **implantable devices and class III devices** claiming equivalence to an already marketed device **not manufactured by him**, in addition to the requirements in MDR Article 61(4), the manufacturer must have a contract in place that allows full access to the technical documentation on an ongoing basis[40]. Furthermore, the MDR also requires that the original clinical evaluation of the equivalent device has been performed in compliance with the requirements of the MDR. This implies that the presumed equivalent device is certified under the MDR. As such, it will not be possible to claim equivalence to a device certified with respect to the Directives 93/42/EEC or 90/385/EEC.

(e) For **devices other than implantable devices and class III devices** and where the manufacturer wants to claim equivalence, MDR Article 61 (3) is applicable. This requirement does not specify whether the device is presumed to be marketed within the EU. Therefore, it will be possible to claim equivalence to a device certified with respect to the Directives 93/42/EEC or 90/385/EEC or the MDR.
However, exceptions can be considered, and equivalence claimed to a device that is not CE-marked, provided all relevant MDR requirements regarding equivalence and clinical evaluation can be met. This includes

- that the manufacturer shall have sufficient levels of access to the data relating to devices with which they are claiming equivalence[41] . In the circumstance that the presumed equivalent device is from another manufacturer, there is no MDR requirement of a contract between the manufacturers for regulating the access to the technical documentation.
- that clinical investigations were conducted in accordance with international guidelines[42]
- that the clinical data meet the requirements of the MDR, and a justification is provided whether the clinical data are transferrable to the European population.

The regulatory status of the presumed equivalent device should be disclosed. See MEDDEV 2.7/1 rev. 4 Appendix A1 for further guidance.

(f) In case of **products without an intended medical purpose** listed in MDR Annex XVI clinical investigations shall be performed for those products unless reliance on existing clinical data from an analogous medical device is duly justified[43]. 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]. To duly justify reliance on existing clinical data from an analogous

[40] MDR, Article 61 (5).
[41] MDR, Annex XIV Part A (3) the last sentence.
[42] MDR, Recital (64)
Clinical investigation of medical devices for human subjects – Good clinical practice (ISO 14155), and World Medical Association Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects.
[43] MDR, Article 61 (9).
[44] MDR, Recital (12).

medical device, the principles of demonstration of equivalence[45] should be applied with the acceptance that the device under evaluation will only have an aesthetic or another non-medical purpose whereas the analogous device has a medical purpose. The general requirement to demonstrate a clinical benefit[46] shall be understood as a requirement to demonstrate the performance of the device.

In addition, since the common specifications (CS) for the products without an intended medical purpose may have requirements related to the clinical evaluation regarding safety[47] these requirements must be taken into consideration when demonstrating equivalence and concluding whether there would be no clinically significant difference in the safety[48].

There shall be no significant difference in the safety and performance between the product and the presumed analogous medical device.

5. Use of data from similar devices

The term 'similar devices' may be understood as devices belonging to the same generic device group. The MDR defines this[49] as 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.

In cases where equivalence cannot be demonstrated under the MDR, the data from similar devices may be useful for a variety of other purposes, for example:

1. Ensuring that the risk management system is comprehensive by identifying relevant hazards and clinical risks.
2. Understanding the state of the art, the natural course of disease and alternative available treatment options.
3. Helping to define the scope of the clinical evaluation, by identifying any design features in similar devices that pose special performance or safety concerns.
4. Provide input for clinical investigation design or post-market clinical follow-up design, and the post-market surveillance system.
5. Identification of relevant and specified clinical outcome parameters for the intended clinical benefits, based on the published clinical data pertaining to the similar device(s).
6. To define minimum requirements for a quantified clinical benefit that is considered clinically relevant, and/or to identify acceptable occurrence rates of risks and adverse events.

[45] MDR, Annex XIV Part A (3).
[46] MDR, Article 61 and Annexes XIV and XV.
[47] MDR, Article 1 (2).
[48] MDR, Annex XIV Part A (3).
[49] MDR, Article 2 (7).

6. Clinical data identification

A clinical evaluation of the device under assessment shall be made according to the MDR[50]. All the clinical data, both favourable and unfavourable shall be identified. This applies to clinical data from both the device in question and the device for which equivalence can be demonstrated. If the data meet the definition of clinical data as defined in the MDR[51], the data shall then progress to data appraisal and analysis in order to evaluate whether the clinical data are providing sufficient clinical evidence for the purpose of confirmation of conformity with the relevant general safety and performance requirements (GSPR)[52].

For identifying, appraising and analysing available clinical data from the scientific literature to establish clinical evidence[53], manufacturers will find facilitative guidance in 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.

[50] MDR, Annex XIV Part A.
[51] MDR, Article 2 (48).
[52] MDR, Annex I.
[53] MDR, Article 2 (51).

Annex I – Equivalence table

A table, such as the table below, may be used to clearly demonstrate equivalence and to identify the supporting data on a device by device basis. The items in the first column of the table are examples only and are to be considered as such. They must not be interpreted as an exhaustive list of specifications, properties, parameters and/or aspects for demonstrating equivalence to another device.

The manufacturer should identify differences and place emphasis on the differences between the two devices rather than the similarities. Considerations shall include the potential additive effect of multiple small differences. For further considerations of equivalence, see sections 3 and 4 in this document.

Scientific justifications shall be provided for the different characteristics when claiming no clinically significant difference in the safety and clinical performance of the device.

Where more than one device is assessed for equivalence, the table should be completed separately for each presumed equivalent device. The documentation of the demonstration of equivalence shall be included in the clinical evaluation report.

Equivalence table **for the comparison of a device with a presumed equivalent marketed device for the purpose of demonstrating equivalence**			
1. Technical characteristics (add a separate row for each of the assessed characteristics)	**Device 1 (under clinical evaluation)** Description of characteristics and reference to specifying documents	**Device 2 (marketed device)** Description of characteristics and reference to specifying documents	**Identified differences or conclusion that there are no differences in the characteristic**
Device is of similar design			1.1
Used under similar conditions of use			1.2
Similar specifications and properties including physiochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength and software algorithms			1.3
Uses similar deployment methods where relevant			1.4
Has similar principles of operation and			1.5

critical performance requirements			

Scientific justification why there would be no clinically significant difference in the safety and clinical performance of the device, OR a description of the impact on safety and or clinical performance (use one row for each of the identified differences in characteristics, and add references to documentation as applicable)	**Clinically significant difference Yes / No**
1.1	
1.2	
1.3	
1.4	
1.5	

2. Biological characteristics (add a separate row for each of the assessed characteristics)	**Device 1** Description of characteristics and reference to specifying documents	**Device 2 (marketed device)** Description of characteristics and reference to specifying documents	**Identified differences or conclusion that there are no differences in the characteristic**
Uses the same materials or substances in contact with the same human tissues or body fluids			(The characteristic must be the same for the demonstration of equivalence) 2.1
Similar kind and duration of contact with the same human tissues or body fluids			2.2
Similar release characteristics of substances including degradation products and leachables			2.3

Scientific justification why there would be no clinically significant difference in the safety and clinical performance of the device, OR a description of the impact on safety and or clinical performance (use one row for each of the identified differences in characteristics, and add references to documentation as applicable)	**Clinically significant difference Yes / No**

2.1			
2.2			
2.3			
3. Clinical characteristics (add a separate row for each of the assessed characteristics)	**Device 1** Description of characteristics and reference to specifying documents	**Device 2 (marketed device)** Description of characteristics and reference to specifying documents	**Identified differences or conclusion that there are no differences in the characteristic**
Same clinical condition or purpose, including similar severity and stage of disease			3.1
Same site in the body			(The characteristic must be the same for the demonstration of equivalence) 3.2
Similar population, including as regards age, anatomy and physiology			3.3
Same kind of user			(The characteristic must be the same for the demonstration of equivalence) 3.4
Similar relevant critical performance in view of the expected clinical effect for a specific intended purpose			3.5
Scientific justification why there would be no clinically significant difference in the safety and clinical performance of the device, OR a description of the impact on safety and or clinical performance (use one row for each of the identified differences in characteristics, and add references to documentation as applicable)			**Clinically significant difference Yes / No**

3.1	
3.2	
3.3	
3.4	
3.5	
Summary In the circumstance that more than one non-significant difference is identified, provide a justification whether the sum of differences may affect the safety and clinical performance of the device.	