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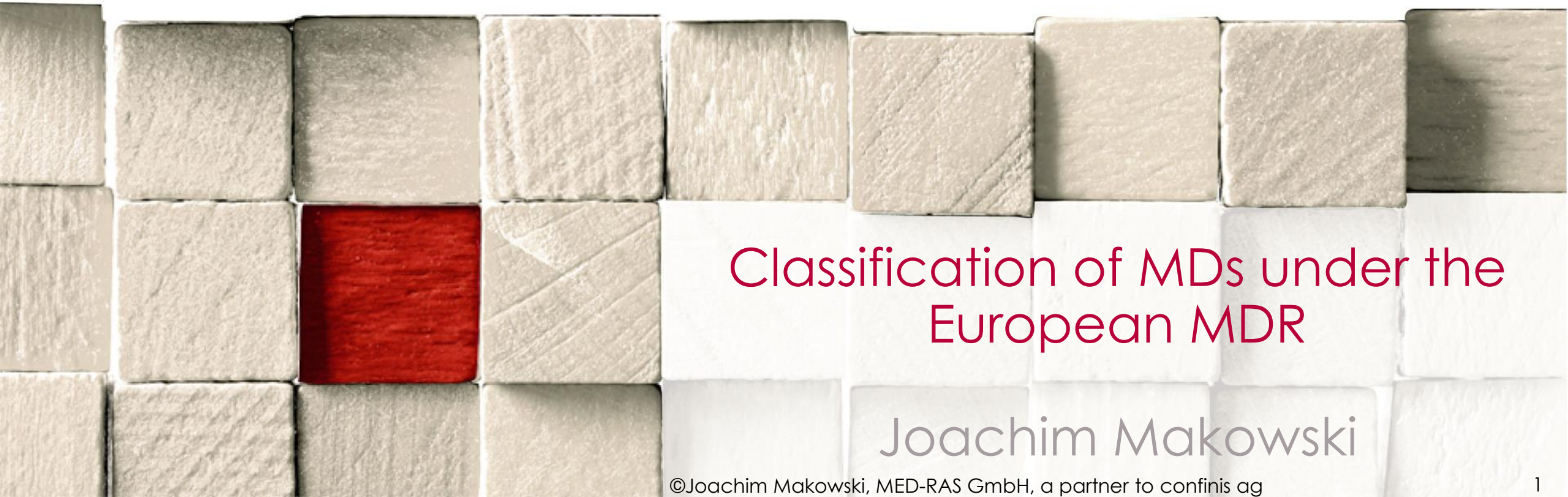

Classification of MDs under the European MDR

Joachim Makowski

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Context of classification

Context of classification

- The purpose of the ‘risk-based’ classification of medical devices is to apply an appropriate conformity assessment procedure.
  - The classification-rules based on the vulnerability of the human body taking account of the potential risks associated with the devices.

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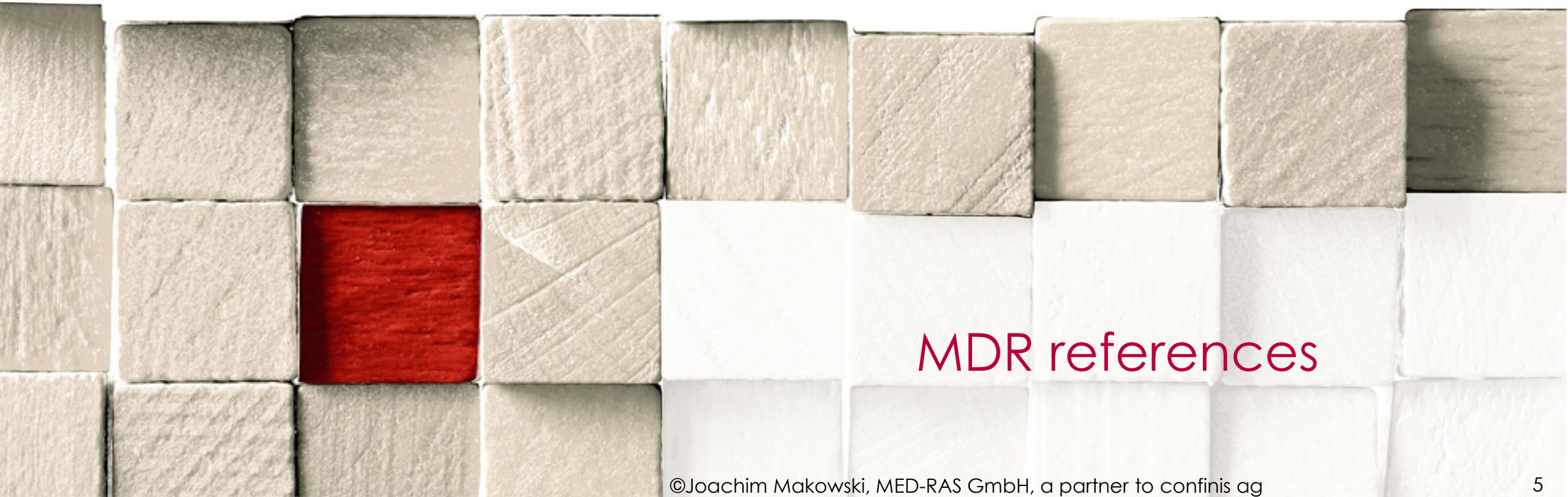

MDR references

MDR references

- Article 51: Classification
  - classification based on rules –> reference to annex VIII
  - approach for clarification of classification in cases of divergent classification results
- ANNEX VIII: Classification Rules

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Key changes

Key changes (1)

- There are **no essential changes in the classification approach** described in article 51.
  - The clarification process and the roles of the different stakeholders in cases of unclear classification is defined more comprehensively than in the MDD

Key changes (2)

- Changes in “Definitions specific to classification rules” (Annex VIII, Chapter I):
  - Definition of “invasive device”, “active device”, “implantable device” are now in Article 2
  - New definition for “injured skin or mucous membrane”

- Changes in “Implementing rules” (Annex VIII, Chapter II):
  - New rule for classification of stand alone software
  - Clarification of criteria for calculation of the duration of “continuous use”
  - New: explanation about the meaning of “device that allows direct diagnosis”

Key changes (3)

- Summary of Changes in Classification Rules (Annex VIII, Chapter III):
  - MDD: 18 classification rules / MDR: 22 classification rules
  - changed wording provides better understanding of the rules
  - Supplemented rules
    - integrate AIMDs into the medical device classification
    - integrate the specific classification for breast implants and joint implants from the EC-Directives 2003/12/EC resp. 2005/50/EC into the MDR
    - provide classification for newly considered specific medical devices, such as (not comprehensive): spinal disc replacement implants, devices with nanomaterial, inhalers, medical devices made from substances

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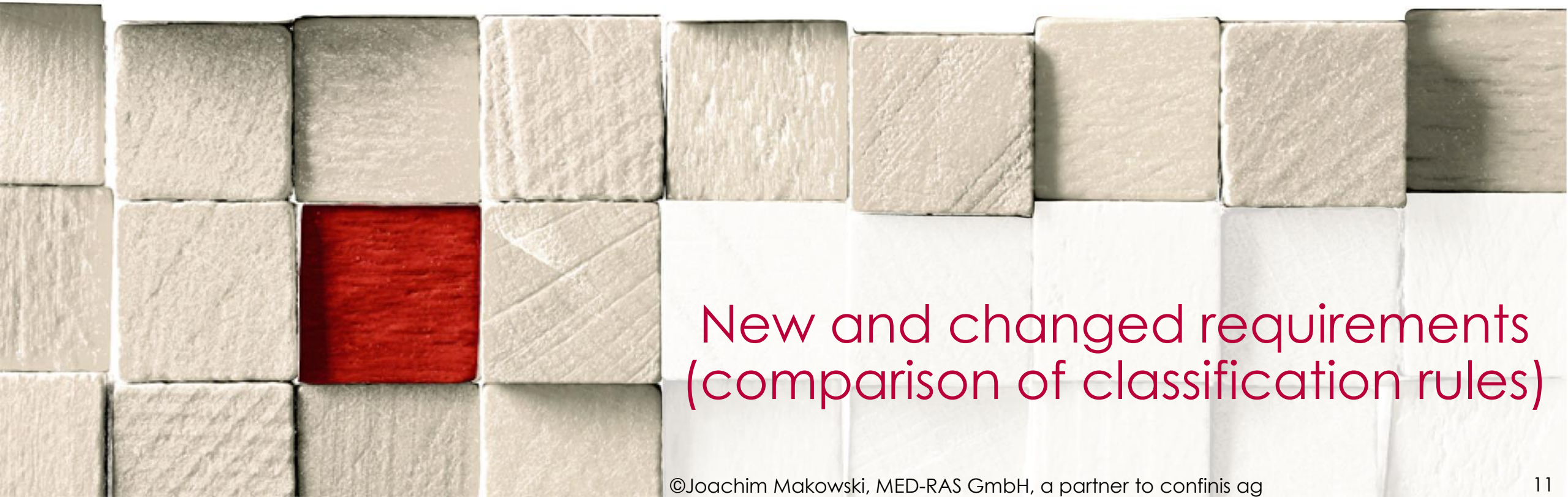

New and changed requirements (comparison of classification rules)

New and changed requirements (comparison of classification rules)

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Rule 1

MDD	**MDR**
All non-invasive devices are in Class I, unless one of the rules set out hereinafter applies.	All non-invasive devices are classified as class I, unless one of the rules set out hereinafter applies.

New and changed requirements (comparison of classification rules)

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Rule 2

MDD	MDR
All non-invasive devices intended for channeling or storing blood, body liquids or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are in Class IIa: • if they may be connected to an active medical device in Class IIa or a higher class, • if they are intended for use for storing or channeling blood or other body liquids or for storing organs, parts of organs or body tissues, in all other cases they are in Class I.	All non-invasive devices intended for channeling or storing blood, body liquids, cells or tissues, liquids or gases for the purpose of eventual infusion, administration or introduction into the body are classified as class IIa: • if they may be connected to a class IIa, class IIb or class III active device; or • if they are intended for use for channeling or storing blood or other body liquids or for storing organs, parts of organs or body cells and tissues, except for blood bags; blood bags are classified as class IIb. (Rule 18 in MDD) In all other cases, such devices are classified as class I.

New and changed requirements (comparison of classification rules)

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Rule 3

MDD	MDR
All non-invasive devices intended for modifying the biological or chemical composition of blood, other body liquids or other liquids intended for infusion into the body are in Class IIb, unless the treatment consists of filtration, centrifugation or exchanges of gas, heat, in which case they are in Class IIa.	All non-invasive devices intended for modifying the biological or chemical composition of human tissues or cells, blood, other body liquids or other liquids intended for implantation or administration into the body are classified as class IIb, unless the treatment for which the device is used consists of filtration, centrifugation or exchanges of gas, heat, in which case they are classified as class IIa. All non-invasive devices consisting of a substance or a mixture of substances intended to be used in vitro in direct contact with human cells, tissues or organs taken from the human body or used in vitro with human embryos before their implantation or administration into the body are classified as class III.

New and changed requirements (comparison of classification rules)

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Rule 4

MDD	MDR
All non-invasive devices which come into contact with injured skin: • are in Class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates, • are in Class IIb if they are intended to be used principally with wounds which have breached the dermis and can only heal by secondary intent, are in Class IIa in all other cases, including devices principally intended to manage the micro-environment of a wound.	All non-invasive devices which come into contact with injured skin or mucous membrane are classified as: • class I if they are intended to be used as a mechanical barrier, for compression or for absorption of exudates; • class IIb if they are intended to be used principally for injuries to skin which have breached the dermis or mucous membrane and can only heal by secondary intent; • class IIa if they are principally intended to manage the micro-environment of injured skin or mucous membrane; and • class IIa in all other cases. This rule applies also to the invasive devices that come into contact with injured mucous membrane.

New and changed requirements (comparison of classification rules)

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Rule 5

MDD	MDR
Invasive Devices	**Invasive Devices**
All invasive devices with respect to body orifices, other than surgically invasive devices and which are not intended for connection to an active medical device or which are intended for connection to an active medical device in Class I: • are in Class I if they are intended for transient use, • are in Class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity, in which case they are in Class I, • are in Class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in a nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are in Class IIa. All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to an active medical device in Class IIa or a higher class, are in Class IIa.	All invasive devices with respect to body orifices, other than surgically invasive devices, which are not intended for connection to an active device or which are intended for connection to a class I active device are classified as: • class I if they are intended for transient use; • class IIa if they are intended for short-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity, in which case they are classified as class I; and • class IIb if they are intended for long-term use, except if they are used in the oral cavity as far as the pharynx, in an ear canal up to the ear drum or in the nasal cavity and are not liable to be absorbed by the mucous membrane, in which case they are classified as class IIa. All invasive devices with respect to body orifices, other than surgically invasive devices, intended for connection to a class IIa, class IIb or class III active device, are classified as class IIa.

New and changed requirements (comparison of classification rules)

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Rule 6

MDD	MDR
All surgically invasive devices intended for transient use are in Class IIa unless they are: • intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III, • reusable surgical instruments, in which case they are in Class I, • intended specifically for use in direct contact with the central nervous system, in which case they are in Class III, • intended to supply energy in the form of ionising radiation in which case they are in Class IIb, • intended to have a biological effect or to be wholly or mainly absorbed in which case they are in Class IIb, • intended to administer medicines by means of a delivery system, if this is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are in Class IIb.	All surgically invasive devices intended for transient use are classified as class IIa unless they: • are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III; • are reusable surgical instruments, in which case they are classified as class I; • are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III; • are intended to supply energy in the form of ionising radiation in which case they are classified as class IIb; • have a biological effect or are wholly or mainly absorbed in which case they are classified as class IIb; or are intended to administer medicinal products by means of a delivery system, if such administration of a medicinal product is done in a manner that is potentially hazardous taking account of the mode of application, in which case they are classified as class IIb.

New and changed requirements (comparison of classification rules)

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Rule 7

MDD	MDR
All surgically invasive devices intended for short-term use are in Class IIa unless they are intended: • either specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with these parts of the body, in which case they are in Class III, • or specifically for use in direct contact with the central nervous system, in which case they are in Class III, • or to supply energy in the form of ionizing radiation in which case they are in Class IIb, • or to have a biological effect or to be wholly or mainly absorbed in which case they are in Class III, • or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class IIb.	All surgically invasive devices intended for short-term use are classified as class IIa unless they: • are intended specifically to control, diagnose, monitor or correct a defect of the heart or of the central circulatory system through direct contact with those parts of the body, in which case they are classified as class III; • are intended specifically for use in direct contact with the heart or central circulatory system or the central nervous system, in which case they are classified as class III; • are intended to supply energy in the form of ionizing radiation in which case they are classified as class IIb; • have a biological effect or are wholly or mainly absorbed in which case they are classified as class III; • are intended to undergo chemical change in the body in which case they are classified as class IIb, except if the devices are placed in the teeth; or • are intended to administer medicines, in which case they are classified as class IIb.

New and changed requirements (comparison of classification rules)

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Rule 8

MDD	MDR
All implantable devices and long-term surgically invasive devices are in Class IIb unless they are intended: • to be placed in the teeth, in which case they are in Class IIa, • to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are in Class III, • to have a biological effect or to be wholly or mainly absorbed, in which case they are in Class III, • or to undergo chemical change in the body, except if the devices are placed in the teeth, or to administer medicines, in which case they are in Class III.	All implantable devices and long-term surgically invasive devices are classified as class IIb unless they: • are intended to be placed in the teeth, in which case they are classified as class IIa; • are intended to be used in direct contact with the heart, the central circulatory system or the central nervous system, in which case they are classified as class III; • have a biological effect or are wholly or mainly absorbed, in which case they are classified as class III; • are intended to undergo chemical change in the body in which case they are classified as class III, except if the devices are placed in the teeth; • are intended to administer medicinal products, in which case they are classified as class III; • are active implantable devices or their accessories, in which cases they are classified as class III; [integration of AIMDs into the MDR] • are breast implants or surgical meshes, in which cases they are classified as class III; [integration of specific classification rule for breast implants from EC-Directive 2003/12/EC] • are total or partial joint replacements, in which case they are classified as class III, with the exception of ancillary components such as screws, wedges, plates and instruments; or [integration of specific classification rule for joint replacement implants from EC-Directive 2005/50/EC] • are spinal disc replacement implants or are implantable devices that come into contact with the spinal column, in which case they are classified as class III with the exception of components such as screws, wedges, plates and instruments. [complete new]

New and changed requirements (comparison of classification rules)

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Rule 9

MDD	MDR
Additional rules applicable to active devices	**[…] Active Devices**
All active therapeutic devices intended to administer or exchange energy are in Class IIa unless their characteristics are such that they may administer or exchange energy to or from the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are in Class IIb. All active devices intended to control or monitor the performance of active therapeutic devices in Class IIb, or intended directly to influence the performance of such devices are in Class IIb.	All active therapeutic devices intended to administer or exchange energy are classified as class IIa unless their characteristics are such that they may administer energy to or exchange energy with the human body in a potentially hazardous way, taking account of the nature, the density and site of application of the energy, in which case they are classified as class IIb. All active devices intended to control or monitor the performance of active therapeutic class IIb devices, or intended directly to influence the performance of such devices are classified as class IIb. All active devices intended to emit ionizing radiation for therapeutic purposes, including devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb. [complete new] All active devices that are intended for controlling, monitoring or directly influencing the performance of active implantable devices are classified as class III. [integration accessories of AIMDs into the MDR]

New and changed Requirements (Comparison of Classification Rules)

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Rule 10

MDD	MDR
Active devices intended for diagnosis are in Class IIa: • if they are intended to supply energy which will be absorbed by the human body, except for devices used to illuminate the patient's body, in the visible spectrum, • if they are intended to image in vivo distribution of radiopharmaceuticals, • if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of CNS in which case they are in Class IIb. Active devices intended to emit ionizing radiation and intended for diagnostic and therapeutic interventional radiology including devices which control or monitor such devices, or which directly influence their performance, are in Class IIb.	Active devices intended for diagnosis and monitoring are classified as class IIa: • if they are intended to supply energy which will be absorbed by the human body, except for devices intended to illuminate the patient's body, in the visible spectrum, in which case they are classified as class I; [clarification – redundant to rule 13] • if they are intended to image in vivo distribution of radiopharmaceuticals; or • if they are intended to allow direct diagnosis or monitoring of vital physiological processes, unless they are specifically intended for monitoring of vital physiological parameters and the nature of variations of those parameters is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of the central nervous system, or they are intended for diagnosis in clinical situations where the patient is in immediate danger, in which cases they are classified as class IIb. Active devices intended to emit ionizing radiation and intended for diagnostic or therapeutic radiology, including interventional radiology devices and devices which control or monitor such devices, or which directly influence their performance, are classified as class IIb.

New and changed requirements (comparison of classification rules)

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Rule 11

MDD	MDR Rule 11
	Software intended to provide information which is used to take decisions with diagnosis or therapeutic purposes is classified as class IIa, except if such decisions have an impact that may cause: • death or an irreversible deterioration of a person's state of health, in which case it is in class III; or • a serious deterioration of a person's state of health or a surgical intervention, in which case it is classified as class IIb. Software intended to monitor physiological processes is classified as class IIa, except if it is intended for monitoring of vital physiological parameters, where the nature of variations of those parameters is such that it could result in immediate danger to the patient, in which case it is classified as class IIb. All other software is classified as class I.

New and changed requirements (comparison of classification rules)

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MDD Rule 11	MDR Rule 12
All active devices intended to administer and/or remove medicines, body liquids or other substances to or from the body are in Class IIa, unless this is done in a manner: • that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are in Class IIb.	All active devices intended to administer and/or remove medicinal products, body liquids or other substances to or from the body are classified as class IIa, unless this is done in a manner • that is potentially hazardous, taking account of the nature of the substances involved, of the part of the body concerned and of the mode of application in which case they are classified as class IIb.

New and changed requirements (comparison of classification rules)

MDD Rule 12	MDR Rule 13
All other active devices are in Class I.	All other active devices are classified as class I.

New and changed requirements (comparison of classification rules)

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MDD Rule 13	MDR Rule 14
All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in Article 1 of Directive 2001/83/EC, and which is liable to act on the human body with action ancillary to that of the devices, are in Class III. All devices incorporating, as an integral part, a human blood derivative are in Class III	All devices incorporating, as an integral part, a substance which, if used separately, can be considered to be a medicinal product, as defined in point 2 of Article 1 of Directive 2001/83/EC, including a medicinal product derived from human blood or human plasma, as defined in point 10 of Article 1 of that Directive [2001/83/EC], and that has an action ancillary to that of the devices, are classified as class III.

New and changed requirements (comparison of classification rules)

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MDD Rule 14	MDR Rule 15
All devices used for contraception or the prevention of the transmission of sexually transmitted diseases are in Class IIb, unless they are implantable or long term invasive devices, in which case they are in Class III.	All devices used for contraception or prevention of the transmission of sexually transmitted diseases are classified as class IIb, unless they are implantable or long term invasive devices, in which case they are classified as class III

New and changed requirements (comparison of classification rules)

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MDD Rule 15	MDR Rule 16
All devices intended specifically to be used for disinfecting, cleaning, rinsing or, when appropriate, hydrating contact lenses are in Class IIb. All devices intended specifically to be used for disinfecting medical devices are in Class IIa. Unless they are specifically to be used for disinfecting invasive devices in which case they are in Class IIb. This rule does not apply to products that are intended to clean medical devices other than contact lenses by means of physical action.	All devices intended specifically to be used for disinfecting, cleaning, rinsing or, where appropriate, hydrating contact lenses are classified as class IIb. All devices intended specifically to be used for disinfecting or sterilising medical devices are classified as class IIa, unless they are disinfecting solutions or washer-disinfectors intended specifically to be used for disinfecting invasive devices, as the end point of processing [clarification], in which case they are classified as class IIb. This rule does not apply to devices that are intended to clean devices other than contact lenses by means of physical action only.

New and changed requirements (comparison of classification rules)

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MDD Rule 16	**MDR Rule 17**
Devices specifically intended for recording of X-ray diagnostic images are in Class IIa.	Devices specifically intended for recording of diagnostic images generated by X-ray radiation are classified as class IIa.

New and changed requirements (comparison of classification rules)

MDD Rule 17	MDR Rule 18
All devices manufactured utilizing animal tissues or derivatives rendered non-viable are Class III except where such devices are intended to come into contact with intact skin only.	All devices manufactured utilizing tissues or cells of human or animal origin, or their derivatives, which are non- viable or rendered non-viable, are classified as class III, unless such devices are manufactured utilizing tissues or cells of animal origin, or their derivatives, which are non-viable or rendered non-viable and are devices intended to come into contact with intact skin only.

New and changed requirements (comparison of classification rules)

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MDD Rule 18	
By derogation from other rules, blood bags are in Class IIb.	[now integrated into MDR rule 2]

New and changed requirements (comparison of classification rules)

	MDR Rule 19
	All devices incorporating or consisting of **nanomaterial** are classified as: • class III if they present a high or medium potential for internal exposure; • class IIb if they present a low potential for internal exposure; and class IIa if they present a negligible potential for internal exposure.

New and changed requirements (comparison of classification rules)

	MDR Rule 20
	All invasive devices with respect to body orifices, other than surgically invasive devices, **which are intended to administer medicinal products by inhalation** are classified as class IIa, unless their mode of action has an essential impact on the efficacy and safety of the administered medicinal product or they are intended to treat life- threatening conditions, in which case they are classified as class IIb.

New and changed requirements (comparison of classification rules)

	MDR Rule 21
	Devices that are **composed of substances or of combinations of substances** that are intended to be introduced into the human body via a body orifice or applied to the skin and that are absorbed by or locally dispersed in the human body are classified as: • class III if they, or their products of metabolism, are systemically absorbed by the human body in order to achieve the intended purpose; • class III if they achieve their intended purpose in the stomach or lower gastrointestinal tract and they, or their products of metabolism, are systemically absorbed by the human body; • class IIa if they are applied to the skin or if they are applied in the nasal or oral cavity as far as the pharynx, and achieve their intended purpose on those cavities; and class IIb in all other cases.

New and changed requirements (comparison of classification rules)

	MDR Rule 22
	Active therapeutic devices with an integrated or incorporated diagnostic function which significantly determines the patient management by the device, such as closed loop systems or automated external defibrillators, are classified as class III. [Automated Control Systems]

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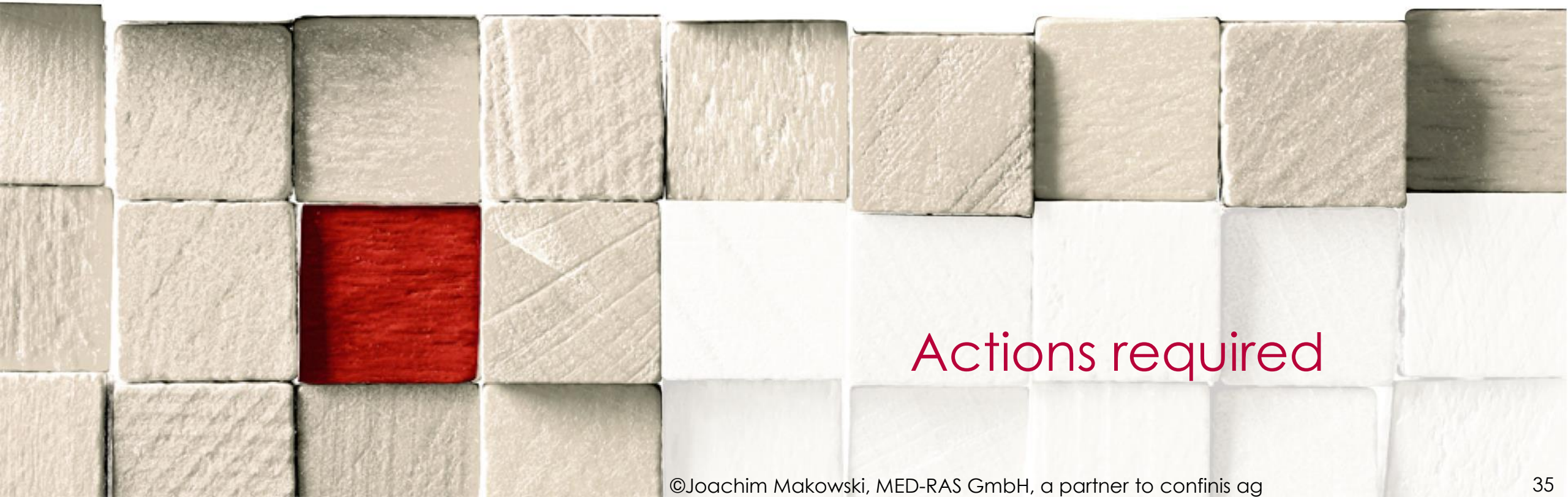

Actions required

Actions required

Actions required to comply with the MDR:

- if new / changed classification rules concern the product portfolio: reclassification and alignment of the conformity assessment procedure if necessary