Risk Management

References to Risk Management

The MDR is in alignment with EN ISO 14971:2012 and EN ISO 13485:2016

Risk, Risk Management or Benefit-Risk is cited over 250 times within the Regulation

Risk is define in Article 2, Definitions as:

> the combination of the probability of occurrence of harm and the severity of that harm

Benefit-Risk Determination is defined in Article 2 as:

> the analysis of all assessments of benefit and risk of possible relevance for the use of the device for the intended purpose, when used in accordance with the intended purpose given by the manufacturer

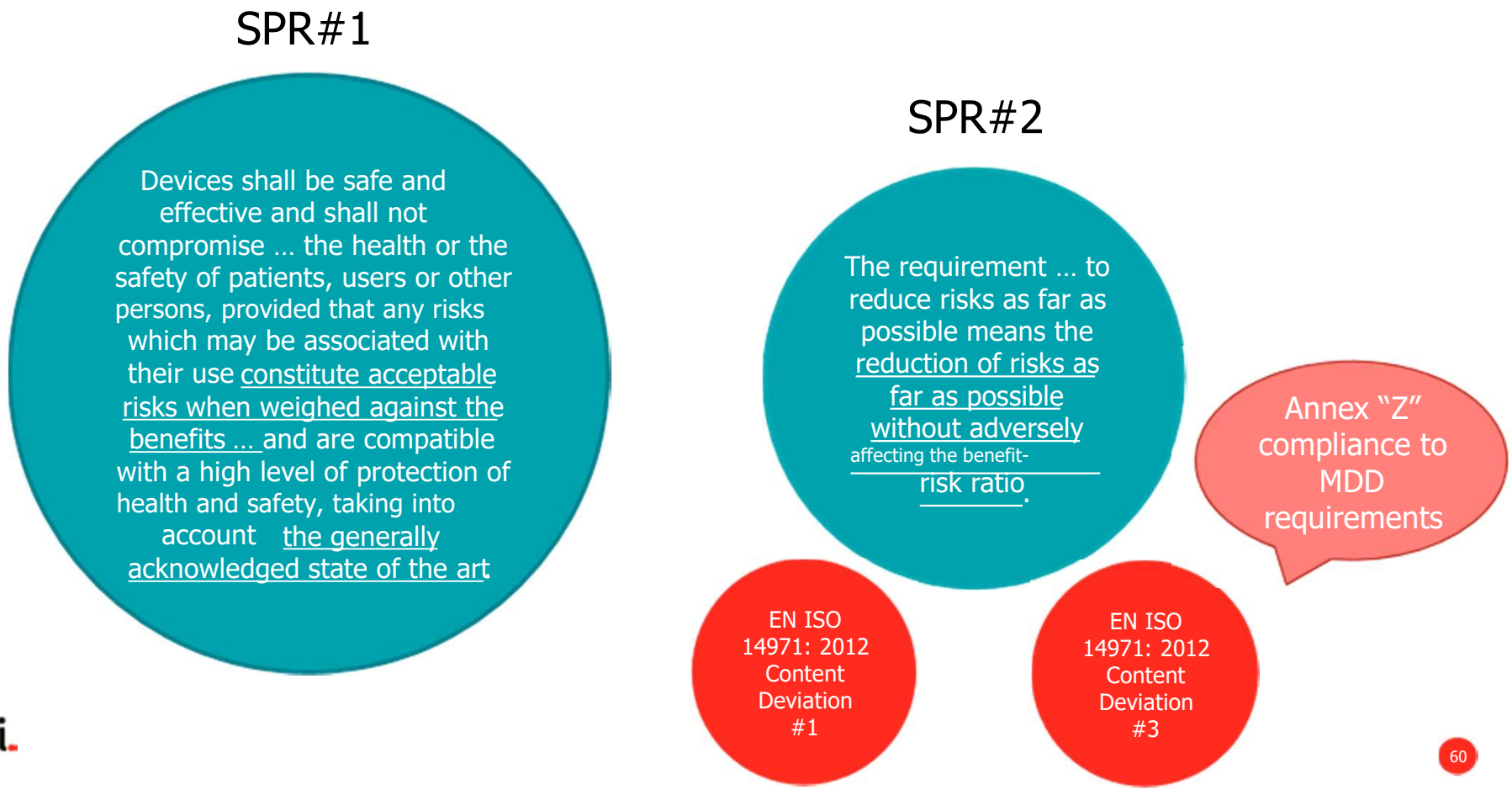
Article 10, General Obligations:

> Manufacturers shall establish, document, implement and maintain a system for risk management as described in Section 3 of Annex I

The Quality Management Systems shall address:

> risk management as set out in in Section 3 of Annex I

Annex I


SPR#1
Devices shall be safe and effective and shall not compromise … the health or the safety of patients, users or other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits … and are compatible with a high level of protection of health and safety, taking into account the generally acknowledged state of the art.
SPR#2
The requirement … to reduce risks as far as possible means the reduction of risks as far as possible without adversely affecting the benefit-risk ratio.
Annex "Z" compliance to MDD requirements
EN ISO 14971: 2012 Content Deviation #1
EN ISO 14971: 2012 Content Deviation #3

Annex I

SPR#3

Manufacturers shall establish, implement, document and maintain a risk management system.

Risk management shall be understood as a continuous iterative process throughout the entire lifecycle of a device, requiring regular systematic updating.

Manufacturers shall:
(a) establish and document a risk management plan for each device;
(b) identify and analyse the known and foreseeable hazards associated with each device;
(c) estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;
(d) eliminate or control the risks referred to in point (c);
(e) evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazards and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk ratio and risk acceptability; and
(f) based on the evaluation of the impact of the information referred to in point (e), if necessary amend control measures in line with the requirements of Section 4.

a) EN ISO 14971:2012 Clause 3.4

b) EN ISO 14971:2012 Clause 4.3

c) EN ISO 14971:2012 Clause 5

d) EN ISO 14971:2012 Clause 6

e) EN ISO 14971:2012 Clause 9

f) EN ISO 14971:2012 Clause 6

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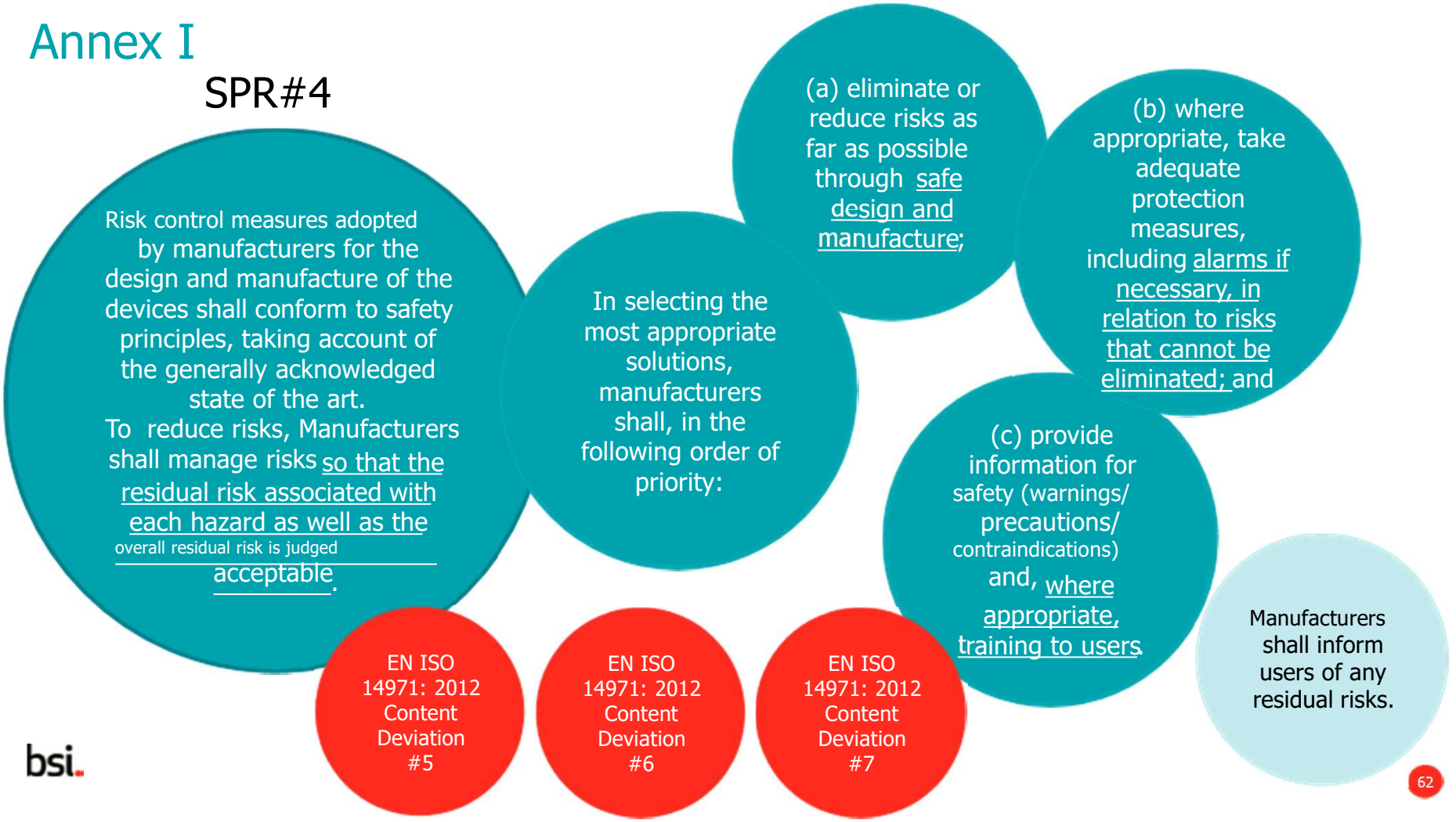
Annex I

SPR#4



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Annex I

SPR#5

In eliminating or reducing risks related to use error, the manufacturer shall:
(a) reduce as far as possible the risks related to the ergonomic features of the device and the environment in which the device is intended to be used (design for patient safety), and
(b) give consideration to the technical knowledge, experience, education, training and use environment, where applicable, and the medical and physical conditions of intended users (design for lay, professional, disabled or other users).

SPR#8

All known and foreseeable risks, and any undesirable side-effects, shall be minimised and be acceptable when weighed against the evaluated benefits to the patient and/or user arising from the achieved performance of the device during normal conditions of use.

EN ISO 14971: 2012 Content Deviation #2

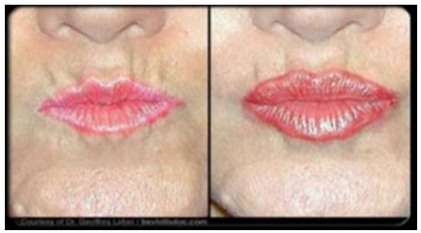
EN ISO 14971: 2012 Content Deviation #4

bsi.

Annex I

SPR#9

For the devices referred to in Annex XVI, the general safety requirements set out in Sections 1 and 8 shall be understood to mean that the device, when used under the conditions and for the purposes intended, **does not present a risk at all** or **presents a risk that is no more than the maximum acceptable risk** related to the product's use which is consistent with a high level of protection for the safety and health of persons.



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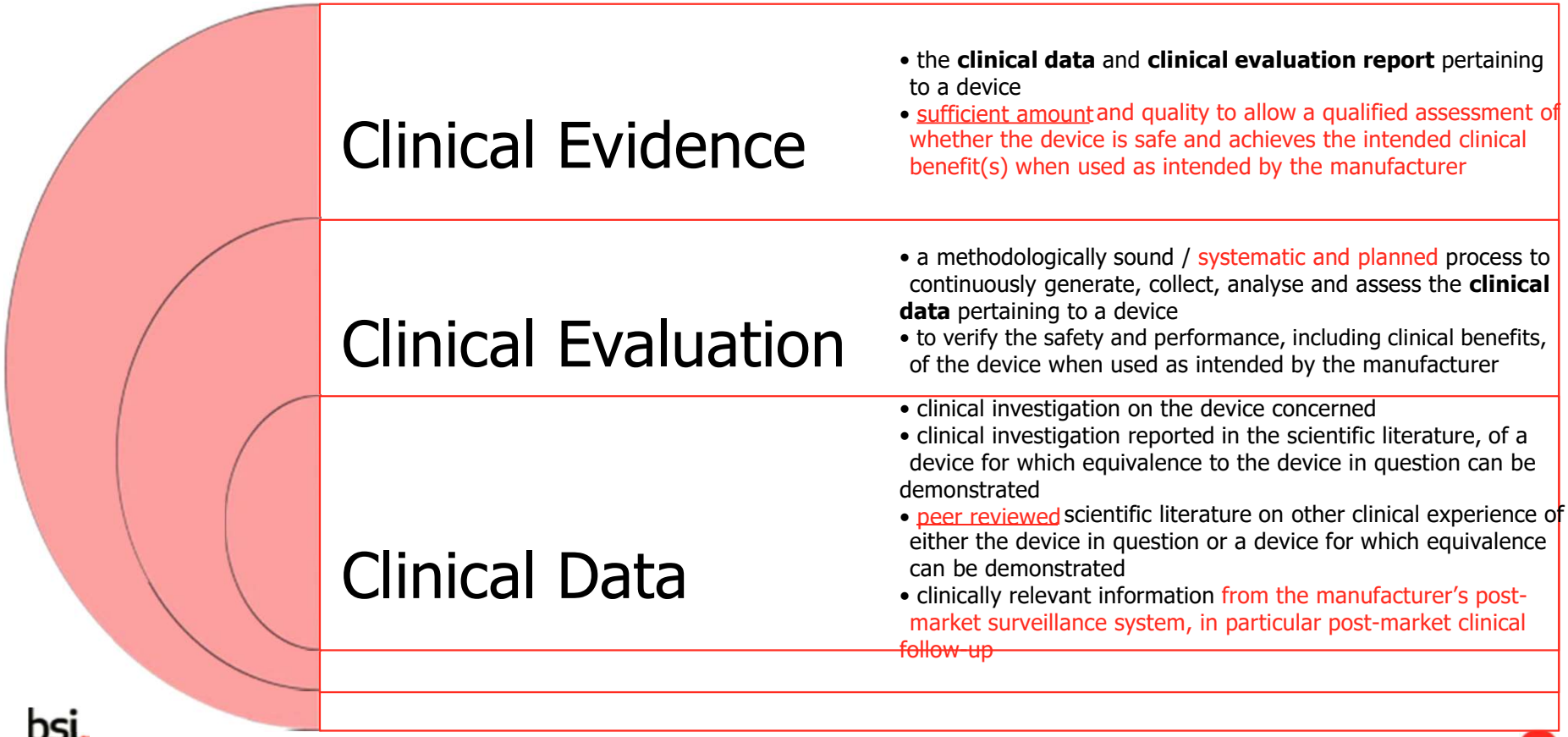
Clinical Evidence

Clinical Evidence – MedDev 2.7.1 & MDR



Equivalence

MedDev 2.7.1 Rev 3 / MedDev 2.7.1 Rev 4 / MDR (Annex XIV) – Equivalence

Technical

- be of similar design
- used under similar conditions of use
- have similar specifications and properties (e.g. physicochemical properties such as intensity of energy, tensile strength, viscosity, surface characteristics, wavelength, software algorithms, porosity, particle size, nanotechnology, specific mass, atomic inclusions – nitrocarburising, oxidability)
- use similar deployment methods (if relevant)
- have similar principles of operation and critical performance requirements

Biological

- use 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
- Exceptions can be foreseen for devices in contact with intact skin and minor components; in these cases risk analysis results may allow the use of similar materials taking into account the role and nature of the similar material. Evaluators should consider biological safety (e.g. ISO 10993) as well as other aspects necessary for a comprehensive demonstration of equivalence. A justification explaining the situation should be provided for any difference.

Clinical

- used for the same clinical condition or intended purpose (including similar severity and stage of disease, medical indication)
- at the same site in the body
- in a similar population (including age, gender, anatomy, physiology)
- have same kind of user
- not foreseen to deliver significantly different performances
- have similar relevant critical performance according to the expected clinical effect for a specific intended purpose

Each device with which equivalence is claimed must fulfil all clinical, technical, biological characteristics

Equivalence and the MDR:

MDR requires the following (Article 61, Clause 5 and 6):

For Class III devices and implants, equivalence can only be claimed with

- The manufacturer's own device
- Other manufacturer's devices if a contract is in place allowing full access to data on an on-going basis

Annex XIV, Section 3:

Appears to indicated that for other classes of devices that only "sufficient level of access" is required to claim equivalence.