GN 16 Guidance on Essential Principles of Safety and Performance of Medical Devices- Key updates

Medical Devices Cluster

23 November 2018

Updates to GN-16 Guidance documents

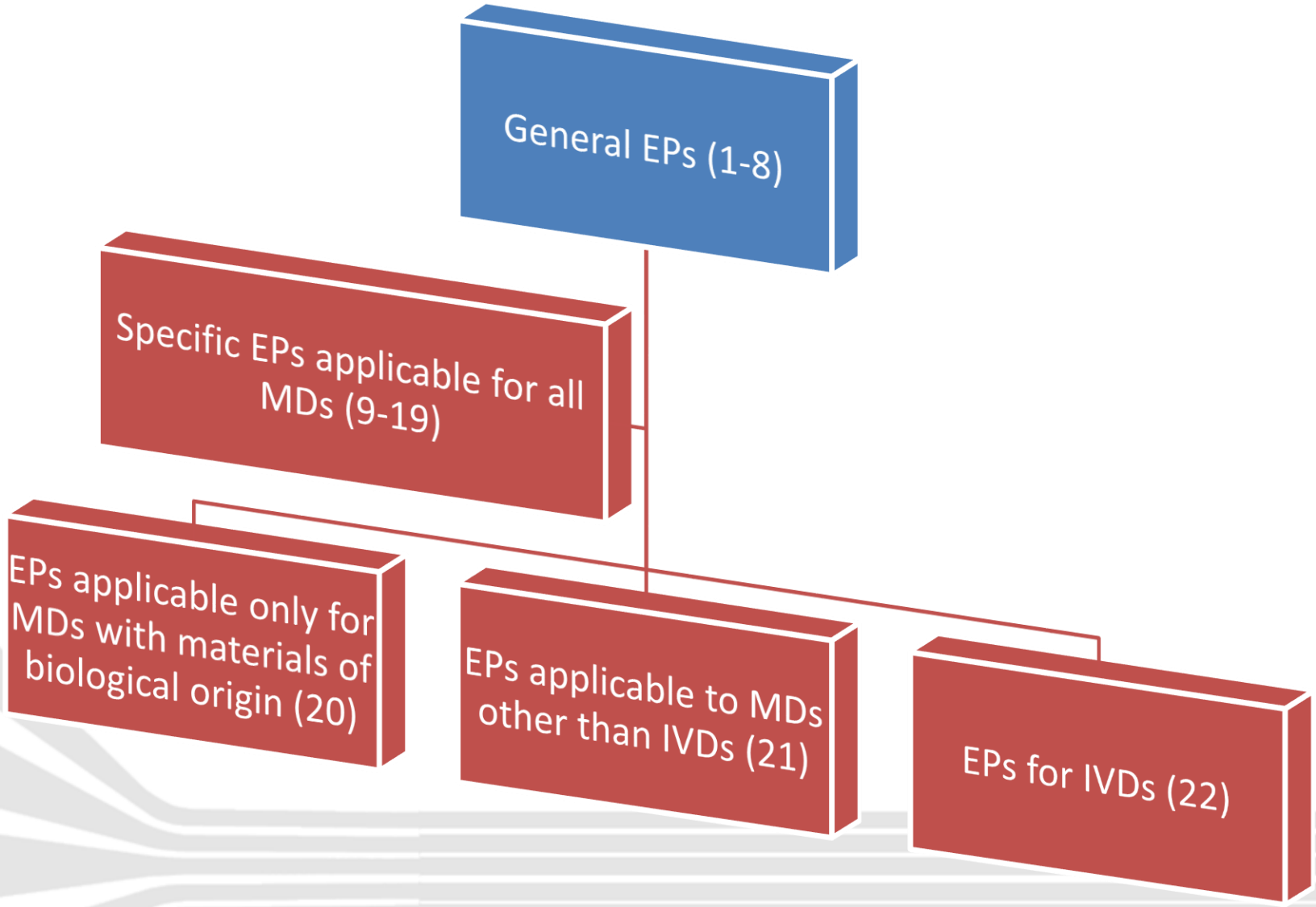
- Updated GN-16 was put up for consult in May 2018 and industry comments were incorporated in the June 2018 version that is available on the HSA website
- GN-16 Guidance describes the fundamental design and manufacturing requirements, for all MDs referred to as 'Essential Principles of Safety and Performance' (EP)
- Flexibility to product owners on how they show conformity to EP
- Standards can be used to reflect conformance to EP
- Tabular checklist of EPs and the corresponding evidence of how the MDs meets the applicable EP is submitted for MD registration (Essential Principles Conformity checklist; EPCC)

GN-16 updates took into account IMDRF guidance on EP, improvements in MD technology as well as to clarify EPs specific for IVDs and combination products

Overview of Updates to GN-16 content

- Re-ordering, merging, renaming of sections
- Addition of definitions
- Updates to phrasing of existing EPs
- New EPs to clarify existing concepts better and address EPs unique to IVDs
- Updated EP conformity checklist (EPCC)

Organisation of EPs



General requirements (1-8)

- 8 general principles regarding design and manufacture of MDs applicable to all MDs

- Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.

1

General requirements (1-8)

- Product owners should establish, implement, document and maintain a risk management system to ensure the ongoing quality, safety and performance of the medical device. Risk management should be understood as a continuous iterative process throughout the entire lifecycle of a medical device, requiring regular systematic updating. In carrying out risk management, product owners should:
  - establish and document a risk management plan for covering each medical device;
  - identify and analyse the known and foreseeable hazards associated with each medical device;
  - estimate and evaluate the risks associated with, and occurring during, the intended use and during reasonably foreseeable misuse;
  - eliminate or control the risks referred to in point (c) in accordance with the requirements of points 3 and 4 below;
  - evaluate the impact of information from the production phase and, in particular, from the post-market surveillance system, on hazardous situations and the frequency of occurrence thereof, on estimates of their associated risks, as well as on the overall risk, benefit-risk determination and risk acceptability; and
  - 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 points 3 and 4 below.

Need for a risk management system that is iterative and up to date

2

General requirements (1-8)

- Risk control measures adopted by the product owner for the design and manufacture of the devices should conform to safety principles, taking account of the generally acknowledged state of the art. When risk reduction is required, the product owner should control the risk(s) so that the residual risk(s) associated with each hazard is judged acceptable. In selecting the most appropriate solutions, product owners should, in the following order of priority:
  - identify known or foreseeable hazards and estimate the associated risks arising from the intended use and foreseeable misuse,
  - eliminate risks as far as reasonably practicable through inherently safe design and manufacture,
  - reduce as low as is reasonably practicable the remaining risks by taking adequate protection measures, including alarms,
  - inform users of any residual risks.
  - provide information for safety (warnings/precautions/contra-indications) and, where appropriate, training to users.

3

- In eliminating or reducing risks related to use, the Product owner should:
  - reduce, as low as is reasonably practicable and appropriate, the risks related to the features of the medical device and the environment in which the medical devices are intended to be used (e.g. ergonomic features, tolerance to dust and humidity) and
  - give consideration to the technical knowledge, experience, education, training and use environment and, where applicable, the medical and physical conditions of intended users.

4

Considerations on risk controls

General requirements (1-8)

- The characteristics and performances of a medical device should not be adversely affected to such a degree that the health or safety of the patient or the user and, where applicable, of other persons are compromised during the expected lifetime of the device, as indicated by the product owner, when the medical device is subjected to the stresses which can occur during intended conditions of use and has been properly maintained and calibrated (if applicable) in accordance with the product owner's instructions.

5

- Medical devices should be designed, manufactured and packaged in such a way that their characteristics and performances, including the integrity and cleanliness of the product and when used in accordance with the intended use, are not adversely affected under transport and storage conditions (for example, through shock, vibrations and fluctuations of temperature and humidity), taking account of the instructions and information provided by the product owner.
- The performance, safety and sterility of the medical devi should be maintained throughout any shelf-life specified by the product

6

- Medical devices should have the stability necessary to maintain essential performance conditions in a period of time and conditions previously established during the shelf-life, during the time of use after being opened (for IVDs, including after being installed in the instrument), and during transportation or dispatch when under conditions other than storage conditions.

7

Characteristics, performances and safety of MDs needs to be maintained throughout transport, storage and life time of the MD

General requirements (1-8)

- All known and foreseeable risks, and any undesirable side-effects, should be minimized and be acceptable when weighed against the evaluated benefits arising from the achieved performance of the medical device during intended conditions of use taking into account the generally acknowledged state of the art.

8

Risks must be minimised and evaluated against benefit and design needs to take into account 'state of art'

9. Clinical Evaluation

3 sections:

All MDs require clinical evidence and evaluation

9.1

- Every medical device requires clinical evidence, appropriate for the use and classification of the device, demonstrating that the device complies with the applicable provisions of the essential principles. A clinical evaluation should be conducted

9.2

- A clinical evaluation should assess clinical data to establish that a favourable benefit-risk determination exists for the medical device in the form of one or more of the following:
  - clinical investigation reports (for IVDs, clinical performance evaluation reports)
  - published scientific literature reviews
  - clinical experience

9.3

- Clinical investigations should be conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki. These principles protect the rights, safety and well-being of human subjects, which are the most important considerations and shall prevail over interests of science and society. These principles shall be understood, observed, and applied at every step in the clinical investigation.

10. Chemical, Physical and Biological properties

4 sections

10.1

The medical devices should be designed and manufactured in such a way as to ensure the characteristics and performance referred to in Clauses 1 to 8 of the 'General Requirements'. Particular attention should be paid to:

the choice of materials used, particularly as regards toxicity and, where appropriate, flammability,

the impact of processes on material properties;

where appropriate, the results of biophysical or modelling research whose validity of which has been demonstrated beforehand;

the compatibility between the materials used and biological tissues, cells, body fluids, and specimens, taking account of the intended purpose of the device,

the choice of materials used should reflect, where appropriate, matters such as strength, ductility, fracture resistance, wear resistance and fatigue resistance.

surface properties; and

the confirm
specificatio

Choice of material used to manufacture the MD, its properties and its compatibility with its intended purpose

10. Chemical, Physical and Biological properties

4 sections

10.2

Minimise risk posed by contaminants/ residues

The medical device should be designed, manufactured and packed in such a way as to minimise the risk posed by contaminants and residues to the persons involved in the transport, storage and use of the devices and to patients, taking account of the intended purpose of the product. Particular attention should be paid to tissues exposed to those contaminants and residues and to the duration and frequency of exposure.

Reduce risk posed by substances leaching/leaking from the device

The devices should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate the risks posed by substances that may leach or leak from the device.

10.3

Reduce risk due to unintentional ingress into the device

The medical device should be designed and manufactured in such a way as to reduce as far as reasonably practicable and appropriate risks posed by the unintentional ingress into the device taking into account the device and the nature of the environment in w[illegible] intended to be used.

10.4

11. Sterility, Packaging and Microbial contamination

- 8 sections:

- Medical devices and their manufacturing processes should be designed in such a way as to eliminate or to reduce as far as reasonably practicable and appropriate the risk of infection to patients, users and, where applicable, all other persons who may come in contact with the medical device.
- The design should:
- allow easy and safe handling,
  - and, where necessary:
- reduce as far as reasonably practicable and appropriate any microbial leakage from the medical device and/or microbial exposure during use;
- prevent microbial contamination of the medical device, or its content (e.g. specimens); and
- reduce as low as reasonably practicable and appropriate the risks from unintended exposure (e.g. cuts and pricks (such as needle stick injuries), eye splashes, etc.).

11.1

- Medical devices labelled as having a special microbiological state should be designed, manufactured and packed to ensure they remain so when placed on the market and remain so under the transport and storage conditions specified by the product owner.

11.2

11. Sterility, Packaging and Microbial contamination

EPs for Sterile MDs

- MDs labelled ‘Sterile’ to remain so when placed on market, transport and storage until protective packaging is opened or damaged

11.3

- MDs labelled ‘Sterile’/’Special microbial state’ to be processed, manufactured and, if applicable, sterilised by appropriate, validated methods. The shelf-life of these medical devices should be determined by validated methods.

11.4

- MDs to be sterilised, must be manufactured and packaged in appropriate and controlled (e.g. environmental) conditions and facilities.

11.5

11. Sterility, Packaging and Microbial contamination

- Packaging systems for non-sterile medical devices should keep the product without deterioration at the level of cleanliness stipulated and, if the devices are to be sterilised prior to use, minimise the risk of microbial contamination; the packaging system should be suitable taking account of the method of sterilisation indicated by the product owner.

11.6

EP for Non-Sterile MDs

- The packaging and/or label of the medical device should distinguish between identical or similar products placed on the market in both sterile and non-sterile condition.

11.7

Labelling must distinguish between sterile and Non-Sterile MDs

- Medical devices meant by the product owner to be reusable, must be designed and manufactured in a way to facilitate appropriate processes to allow reuse, including cleaning, disinfection, packaging and where appropriate, the method of re-sterilisation. The instructions for use should provide information to identify when the device should no longer be reused (e.g. when there are signs of material degradation or the maximum number of allowed reuses).

11.8

EP for reusable MDs

12. Considerations of Environment and Conditions of Use

6 sections:

12.1

- Medical devices should be designed and manufactured in such a way as to eliminate or reduce, as low as reasonably practicable and appropriate, the :
  - risks of injury, in connection with their physical features, including the volume/pressure ratio, dimensional and where appropriate ergonomic features;
  - risks of user error due to the design of the medical device user interface, ergonomic features, and the environment in which the medical device is intended to be used;
  - risks connected with reasonably foreseeable external influences or environmental conditions, such as magnetic fields, external electrical and electromagnetic effects, electrostatic discharge, pressure, humidity, temperature or variations in pressure and acceleration;
  - risks connected to their use in conjunction with materials, substances and ga
    which they may come into contact during intended conditions of use;
  - risks associated with the possible negative interaction between softw
    information technology (IT) environment within which it operates ar
  - environmental risks from unexpected egress of substances from th
    use, taking into account the medical device and the nature of the e
    is intended to be used;
  - risks of incorrect identification of specimens;
  - risks of reciprocal interference with other medical devices normally us
    monitoring or for the treatment given.

All risks that need to be kept in mind regarding the environment and use of the MD

12. Considerations of Environment and Conditions of Use

6 sections:

- Medical devices should be designed and manufactured in such a way as to eliminate or reduce, as low as reasonably practicable and appropriate, the risks of fire or explosion during normal use and in single fault condition. Particular attention should be paid to devices whose intended use includes exposure to or use in association with flammable substances or substances which could cause combustion.

12.2

Fire safety

- Medical devices should be designed and manufactured in such a way that adjustment, calibration, and maintenance can be done safely and effectively. Specifically,
- when maintenance is not possible (e.g. with implants), the risks from ageing of materials used, will be eliminated or reduced, as low as reasonably practicable and appropriate).
- when adjustment and calibration are not possible (e.g. with certain kinds of thermometers), the risks from loss of accuracy of any measuring or control mechanism will be eliminated or reduced, as low as reasonably practicable and appropriate.

12.3

Maintenance and calibration

12. Considerations of Environment and Conditions of Use

6 sections:

- If the device is intended for use in combination with other devices or equipment, the whole combination, including the connection system should be safe and should not impair the specified performance of the devices. Any restrictions on use applying to such combinations should be indicated on the label and/or in the instructions for use.

12.4

Considerations on the other systems that the MD is intended to be connected to

- Any measurement, monitoring or display scale should be designed and manufactured in line with ergonomic principles, taking account of the intended purpose, users and the environmental conditions in which the medical devices are intended to be used.

12.5

Ergonomics

- Medical devices must be designed and manufactured in such a way as to facilitate their safe disposal and the safe disposal of any waste substances by the user, patient or other person. The instructions for use should identify safe disposal procedures and measures.

12.6

Safe disposal

13. Active medical devices connected to or equipped with an energy source

5 sections:

- Medical devices where the safety of the patients depends on an internal power supply should be equipped with a means of determining the state of the power supply and an appropriate warning or indication for when the capacity of the power supply becomes critical.

13.1 Indicators of internal battery life

- Medical devices where the safety of the patients depends on an external power supply should include an alarm system to signal any power failure.

13.2 Need for alarms to signal failure of external power supply

- Medical devices intended to monitor one or more clinical parameters of a patient should be equipped with appropriate alarm systems to alert the user of situations which could lead to death or severe deterioration of the patient's state of health.

13.3 Alarms for critical clinical parameters

13. Active medical devices connected to or equipped with an energy source

5 sections:

- Medical devices should be designed and manufactured in such a way as to eliminate or reduce, as low as reasonably practicable and appropriate, the risks of creating electromagnetic interference which could impair the operation of this or other devices or equipment in the intended environment.

13.4

Reduce risk of creating electromagnetic interference

- Medical devices should be designed and manufactured in such a way as to provide an adequate level of intrinsic immunity to electromagnetic disturbance to enable them to operate as intended.

13.5

Immunity from electromagnetic interference

14. Medical devices that incorporate software or are standalone software or mobile applications

4 sections:

- Medical devices that incorporate electronic programmable systems, including software, or are standalone software or mobile applications, should be designed to ensure accuracy, reliability, precision, safety, and performance in line with their intended use. In the event of a single fault condition, appropriate means should be adopted to eliminate or reduce, as far as possible and appropriate, consequent risks or impairment of performance.

14.1

- For medical devices that incorporate software or are standalone software or mobile applications, the software should be developed, manufactured and maintained in accordance with the state of the art taking into account the principles of development life cycle (e.g. rapid development cycles, frequent changes, the cumulative effect of changes), risk management (e.g. changes to system, environment, and data), including information security (e.g. safely implement updates), verification and validation (e.g. change management process).

14.2

14. Medical devices that incorporate software or are standalone software or mobile applications

4 sections:

- Software that is intended to be used in combination with generic computing platforms should be designed and developed taking into account the platform itself (e.g. size and contrast ratio of the screen, connectivity, memory, etc.) and the external factors related to their use (varying environment as regards level of light or noise).

14.3

- Product owner should set out minimum requirements concerning hardware, IT networks characteristics and IT security measures, including protection against unauthorised access, necessary to run the software as intended.

14.4

15. Medical devices with a diagnostic or measuring function

1 section:

- Medical devices with a diagnostic or measuring (including monitoring) function, where inaccuracy could have a significant adverse effect on the patient, should be designed and manufactured in such a way as to provide sufficient accuracy, precision and stability for their intended purpose of the device.
- Where applicable, the limits of accuracy should be indicated by the product owner.
- Whenever possible, values expressed numerically should be in commonly accepted, standardised units, and understood by users of the medical device.
- The function of the controls and indicators should be clearly specified on the medical device. Where a medical device bears instructions required for its operation or indicates operating or adjustment parameters by means of a visual system, such information should be understandable to the user and, as appropriate, the patient.

15.1

16. Labelling and Instructions for Use

For additional guidance on the contents of the label and instructions for use, please refer to GN-23 Guidance on Labelling for Medical Devices.

2 sections:

- Each medical device should be accompanied by the information needed to identify the medical device and its product owner. Each medical devices should also be accompanied by, or direct the user to any safety and performance information relevant to the user, or any other person, as appropriate. Such information may appear on the medical device itself, on the packaging or in the instructions for use, and should be easily understood.

16.1

- The medium, format, content, legibility, and location of the label and instructions for use should be appropriate to the particular medical device, its intended purpose and the technical knowledge, experience, education or training of the intended users. Instructions for use should be written in terms readily understood by the intended user and, where appropriate, supplemented with drawings and diagrams. If instructions for use are insufficient, appropriate training should be provided. Some medical devices should include separate information for the professional user and the lay person.

16.2

17. Protection against electrical risks, mechanical and thermal risks

9 sections:

- 17.1 Risk of electric shock
- 17.2 17.3 Unauthorised access: Cybersecurity and safety risks
- 17.4 Risk from moving parts
- 17.5 Risk from vibrations
- 17.6 Risk from noise
- 17.7 17.8 Accurate connections
- 17.9 Risk from dangerous temperature

18. Protection against radiation

7 sections:

- **18.1** Risk of emitted radiation
- **18.2** Operating instructions-Protection
- **18.3** Visual/Audible warnings
- **18.4** Risk from unintended/stray radiation
- **17.5** Quality of diagnostic imaging while minimizing radiation exposure
- **18.6** Information on proper installation, testing and maintenance
- **18.7** Need to appropriately and reproducibly vary, control and monitor

19. Protection against the risks posed by medical devices intended for use by lay persons

3 sections:

19.1

- Medical devices for use by lay persons (such as self-testing or near-patient testing) should be designed and manufactured in such a way that they perform appropriately for their intended purpose taking into account the skills and the means available to lay persons and the influence resulting from variation that can reasonably be anticipated in lay person's technique and environment. The information and instructions provided by the product owner should be easy for the lay person to understand and apply when using the medical device and interpreting the results.

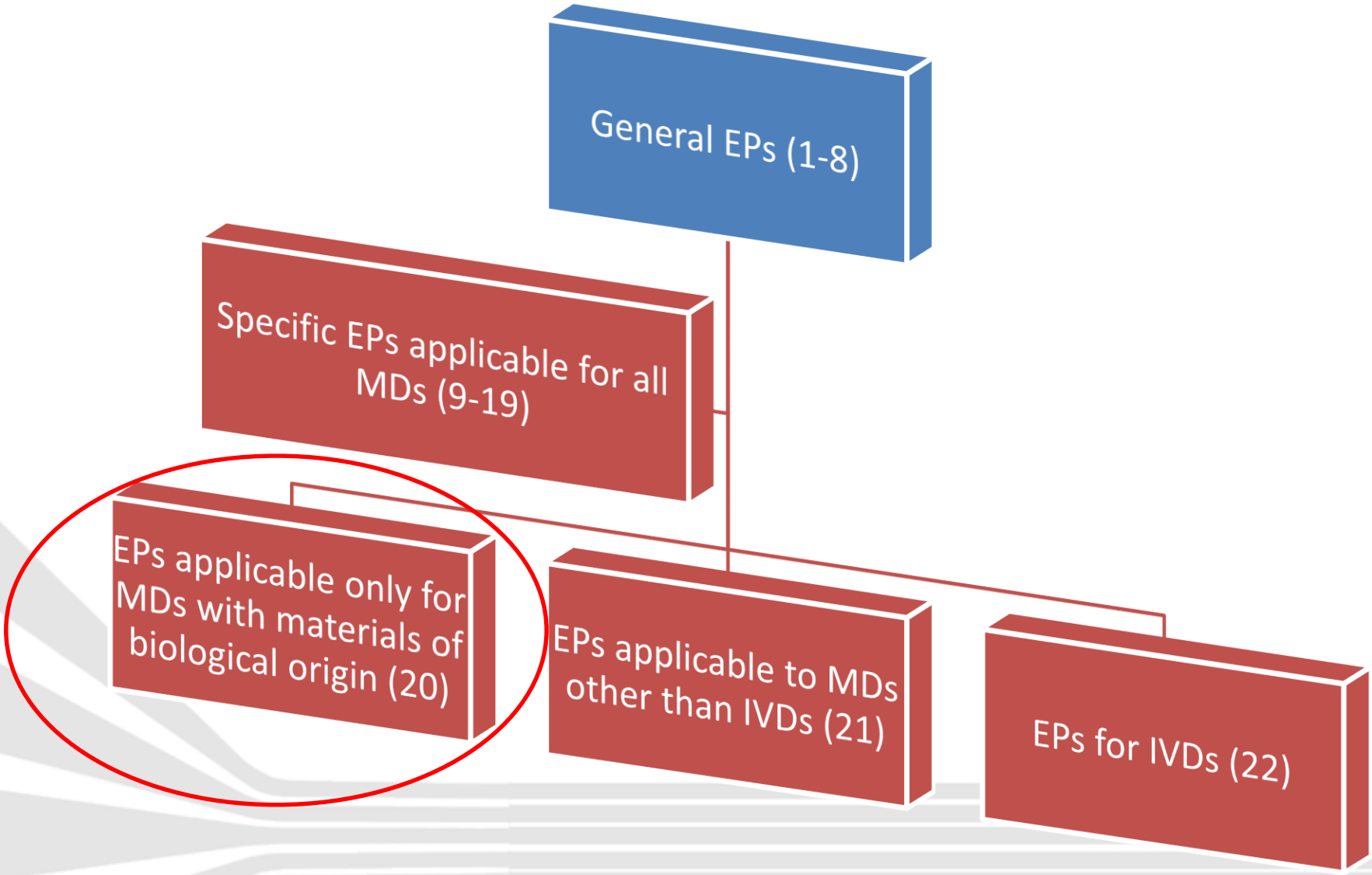
19.2

- Medical devices for use by lay persons (such as self-testing or near-patient testing) should be designed and manufactured in such a way as to:
- ensure that the medical device can be used safely and accurately by the intended user per instructions for use. If instructions for use are insufficient, appropriate training should be provided.
- reduce, as low as reasonably practicable and appropriate, the risks of error by the intended user in the handling of the medical device and, if applicable, in the interpretation of the results

19.3

- Medical devices for use by lay persons (such as self-testing or near-patient testing) should, where appropriate, include means by which the lay person:
- can verify that, at the time of use, the medical device will perform as intended by the product owner, and
- is warned if the medical device has failed to operate as intended or to provide a valid result

Organisation of EPs



20. Medical devices incorporating materials of biological origin

3 sections:

20.1

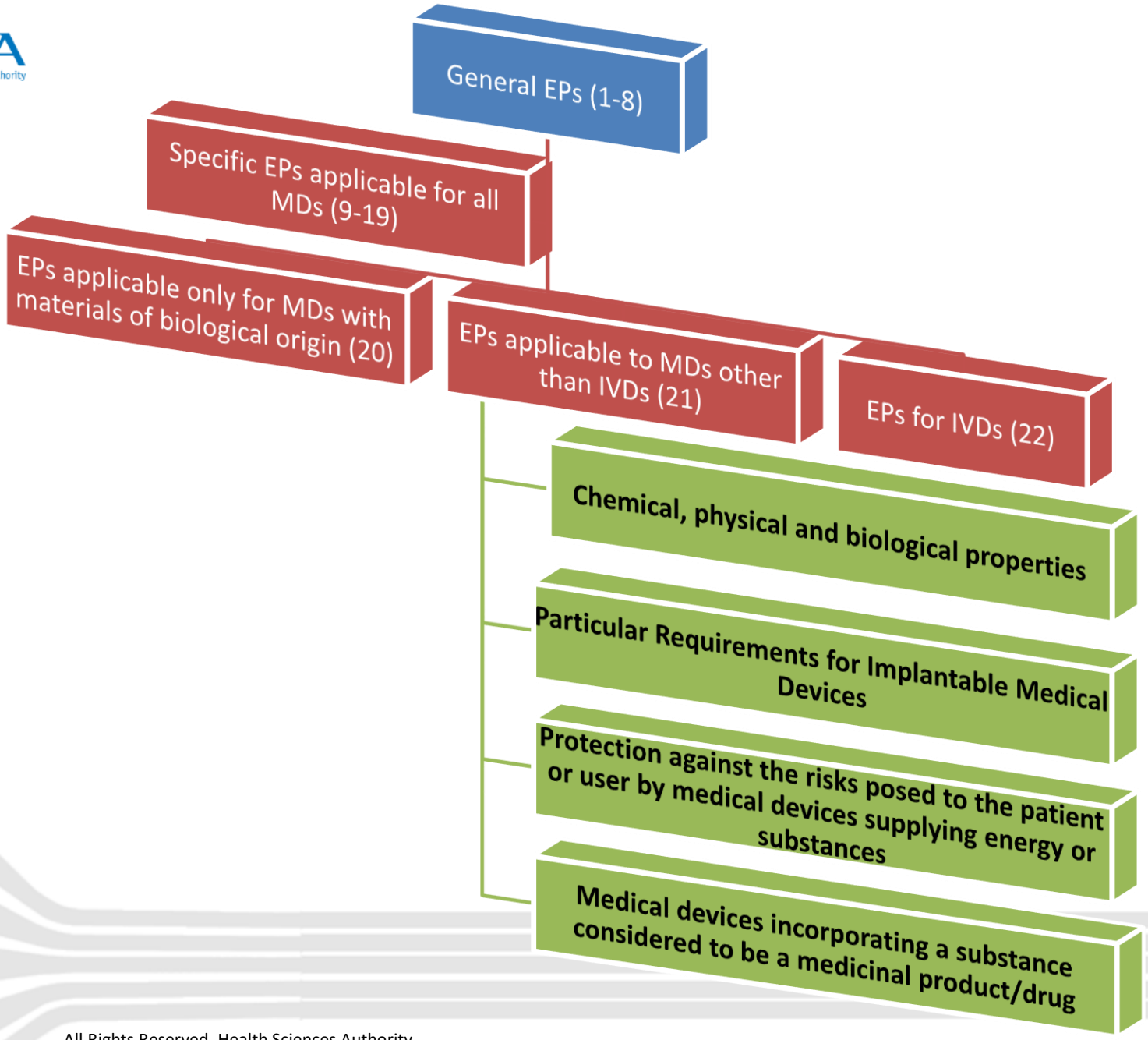
- For medical devices that incorporate tissues, cells, or substances of animal origin, or their derivatives, which are non-viable or rendered non-viable the following should apply:
- where feasible, taking into account the animal species, tissues and cells of animal origin, or their derivatives, should originate from animals that have been subjected to veterinary controls that are adapted to the intended use of the tissues. The product owner is required to retain information on the geographical origin of the animals.
- sourcing, processing, preservation, testing and handling of tissues, cells and substances of animal origin, or their derivatives, should be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regards to viruses and other transmissible agents should be addressed by implementation of validated state of the art methods of elimination or inactivation in the course of the manufacturing process, except when the use of such methods would lead to unacceptable degradation compromising the medical device.

20.2

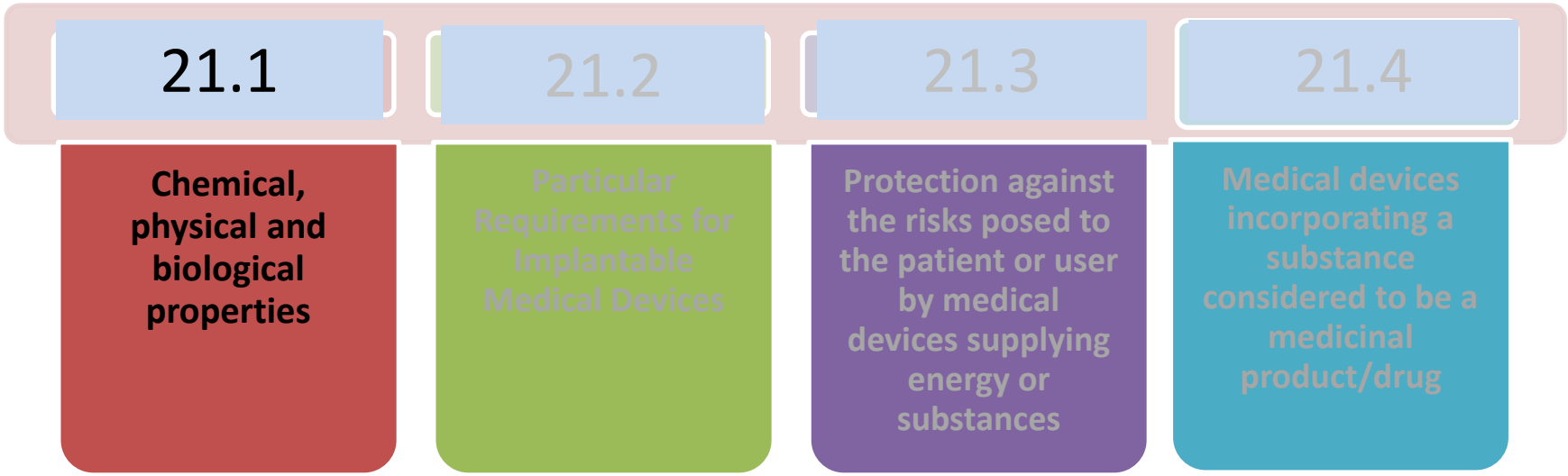
- For products that incorporate tissues, cells, or substances of human origin or their derivatives as medical devices, the following should apply:
- donation, procurement and testing of the tissues and cells should be done in accordance with jurisdictional requirements; and
- processing, preservation and any other handling of those tissues and cells or their derivatives should be carried out so as to provide safety for patients, users and, where applicable, other persons. In particular, safety with regard to viruses and other transmissible agents should be addressed by appropriate methods of sourcing and by implementation of validated state of the art methods of elimination or inactivation in the course of the manufacturing process.

20.3

- For medical devices manufactured utilising non-viable biological substances other than those referred to in Clauses 20.1 and 20.2, the processing, preservation, testing and handling of those substances should be carried out so as to provide safety for patients, users and, where applicable, other persons, including in the waste disposal chain. In particular, safety with regards to viruses and other transmissible agents should be addressed by appropriate methods of sourcing and by implementation of validated state of the art methods of elimination or inactivation in the course of the manufacturing process.



20. Essential principles applicable to medical devices other than IVD medical devices



21.1.1 • Compatibility to biological tissues

21.1.2 • Can be used safely with the materials/ substances/gases, they contact

21.1.3 • Eliminate or reduce, risks of particles released into the patient's or user's body

20. Essential principles applicable to medical devices other than IVD medical devices

21.1	21.2	21.3	21.4
Chemical, physical and biological properties	**Particular Requirements for Implantable Medical Devices**	Protection against the risks posed to the patient or user by medical devices supplying energy or substances	Medical devices incorporating a substance considered to be a medicinal product/drug

21.2.1

- Implantable medical devices should be designed and manufactured in such a way as to eliminate or reduce, as low as reasonably practicable and appropriate, the risks connected with medical treatment (e.g. the use of defibrillators, high-frequency surgical equipment).

21.2.2

- Active programmable implantable medical devices should be designed and manufactured in a manner that allows the unequivocal identification of the device without the need for a surgical operation.

20. Essential principles applicable to medical devices other than IVD medical devices

21.1	21.2	21.3	21.4
Chemical, physical and biological properties	Particular Requirements for Implantable Medical Devices	**Protection against the risks posed to the patient or user by medical devices supplying energy or substances**	Medical devices incorporating a substance considered to be a medicinal product/drug

21.3.1

- Medical devices for supplying the patient with energy or substances should be designed and manufactured in such a way that the amount to be delivered can be set and maintained accurately enough to ensure the safety of the patient, user, and others.

21.3.2

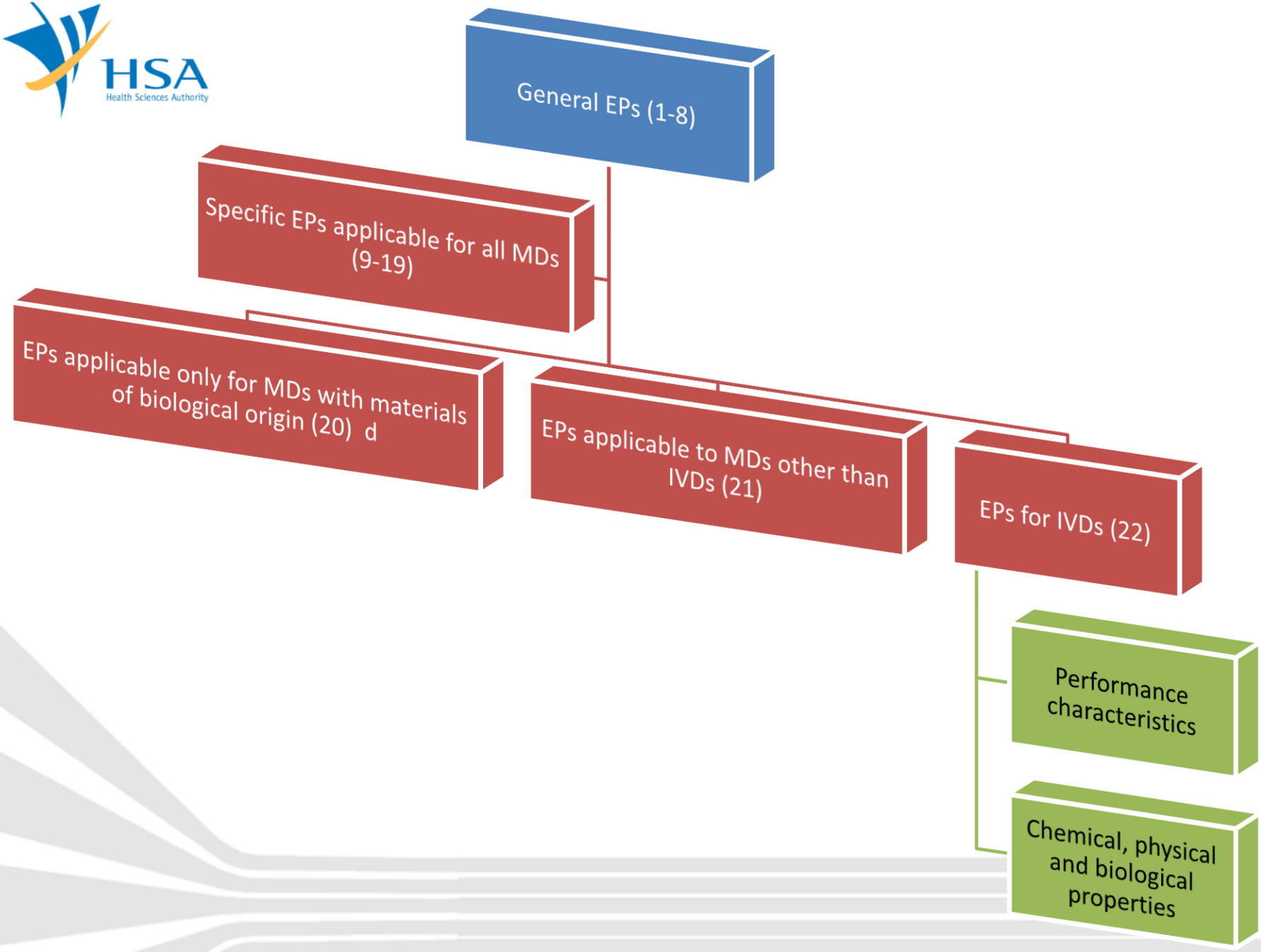
- Medical devices should be fitted with the means of preventing and/or indicating any inadequacies in the amount of energy delivered or substances delivered which could pose a danger. Devices should incorporate suitable means to prevent, as far as possible, the accidental release of dangerous levels of energy or substances from an energy and/or substance source.

20. Essential principles applicable to medical devices other than IVD medical devices

21.1	21.2	21.3	21.4
Chemical, physical and biological properties	Particular Requirements for Implantable Medical Devices	Protection against the risks posed to the patient or user by medical devices supplying energy or substances	**Medical devices incorporating a substance considered to be a medicinal product/drug**

21.4.1

- Where a medical device incorporates, a substance which, if used separately may be considered to be a medicinal product/drug and which is liable to act upon the body with action ancillary to that of the medical device, the safety and performance of the medical device as a whole should be verified, as well as the identify, safety, quality and efficacy of the substance in the specific combination product if dose, mechanism of action and intended use of the substance is similar to that of medicinal product when used separately.



22.1 Performance characteristics

5 sub-sections:

- **22.1.1** The analytical and clinical performances must match the intended use/user /settings
- **22.1.2** Clinical performance
- **22.1.3** Value assignment to calibrators and controls
- **22.1.4** Use of standardized units
- **22.1.5** How to evaluate performance characteristics

22.2 Chemical, Physical and Biological properties

- With regards to chemical, physical, and biological properties for IVD medical devices, attention should be paid to the possibility of impairment of analytical performance due to physical and/or chemical incompatibility between the materials used and the specimens, analyte or marker to be detected (such as biological tissues, cells, body fluids and micro-organisms), taking account of the intended purpose of the device.

22.2.1

To identify possible interfering substances that can affect the IVD result

SG Essential Principles Conformity Checklist- GN-16 Annex 2

Annex 2

Singapore Essential Principles Conformity Checklist Template (June 2018 version)

EP Checklist control number:
Product Owner Name:
Product Name:

No.	Essential Principles – General requirements	Applicable to the device?	Method of Conformity	Identity of Specific Documents
1.	Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.			
2.	Product owners should establish, implement, document and maintain a risk management system to ensure the ongoing quality, safety and performance of the medical device. Risk management should be understood as a continuous iterative process throughout the entire lifecycle of a medical device, requiring regular systematic updating. In carrying out risk management, product owners should:			

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SG Essential Principles Conformity Checklist- GN-16 Annex 3

Annex 3

Singapore Essential Principles Conformity Checklist Template (December 2017 version)

NOTE: This is the earlier version of the Singapore Essential Principles conformity checklist (Dec 2017 version) which will continue to be accepted for purposes of registration in Singapore. Registrants may choose to submit either version of the Singapore Essential Principles conformity checklist (i.e. Annex 2 or Annex 3) for device registration in Singapore. Essential Principles conformity checklists prepared for approvals or clearance from our reference regulatory agency jurisdictions will continue to be accepted for device registration in Singapore.

EP Checklist control number:
Product Owner Name:
Product Name:

No.	Essential Principles – General requirements	Applicable to the device?	Method of Conformity	Identity of Specific Documents
1.	Medical devices should be designed and manufactured in such a way that, when used under the conditions and for the purposes intended and, where applicable, by virtue of the technical knowledge, experience, education or training of intended users, they will not compromise the clinical condition or the safety of patients, or the safety and health of users or, where applicable, other persons, provided that any risks which may be associated with their use constitute acceptable risks when weighed against the benefits to the patient and are compatible with a high level of protection of health and safety.			

Conclusions

(1) Updated GN16:

- Re-ordering, merging, renaming of sections
- Addition of definitions
- Updates to phrasing of existing EPs
- New EPs to clarify existing concepts better and address EPs unique to IVDs

(2) EPCC formats accepted for registration in SG:

- SG EPCC GN-16 Annex 2 (Jun 2018 version)
- SG EPCC GN-16 Annex 2 (Dec 2017 version)
  - EU EPCC
  - TGA EPCC