The European Association of Medical devices Notified Bodies

Team-NB Position Paper

Editor :	**Team-NB**	Adoption date 15/12/2023	Version 1

Medical Device Lifetime

Introduction

Article 2 of the Medical Devices Regulation 2017/745[1] (MDR) includes definitions for; 'medical device', 'making available on the market', 'placing on the market', 'putting into service' but not one specifically for the medical device lifetime.

The general safety and performance requirements (GSPR) of MDR Annex I include GSPR 6 for the characteristics and performance of a device not to be adversely affected to such an extent that health and safety of the patient, or user or of other persons are compromised during device lifetime as indicated by the manufacturer when the device is subjected to normal conditions of use and has been maintained to manufacturers' instructions. This implies that manufacturers must indicate a lifetime for the device, and where applicable, provide maintenance instructions for the device.

There are other requirements in the MDR related to the lifetime of medical devices, for example in Article 18 for implantable devices, Article 83 and 86 for post market surveillance and Annex XIV Part B sections 5 and 6, and Annex II (6) shelf life. GSPR 23.4 information in the instructions for use instructions for calibration, to ensure the device operates properly and safely and labelling such a UDI carrier readability. As such, the indication of a lifetime for a device by the manufacturer is needed to demonstrate how compliance with these various requirements, are met.

As there is no specific definition for device lifetime within the regulatory text, this position paper is intended to promote consistency in approach, to provide an overview of existing guidance and standards, to identify expectations and illustrate the matter for different device types.

[1] Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC

Presently Available guidance

The Medical Device Co-ordination Group MDCG 2022-21[2] Periodic Safety Update Report (PSUR) guidance, states that the lifetime of a device is the time-period specified by the manufacturer in the device documentation during which the device is expected to remain safe and effective for use / in use. For PSUR purposes, MDCG 2022-21 indicates the overall lifetime of the device (model) as being the time of the last manufactured device of the device model being placed on the market plus the intended lifetime of that (individual) device.

Another guidance, MDCG 2020-8[3], Post-Market Clinical Follow-up (PMCF) has a foot note that the expected lifetime is to be defined during the design input phase by considering the current state of the art for a specific intended use and indication of a device.

In prior guidance from the International Medical Device Regulators Forum (IMDRF) [4], of Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices section 3.1.3 defines expected lifetime or expected service life as the time period specified, by the manufacturer during which the medical device or IVD medical device is expected to maintain safe and effective use with notes that this expected lifetime can be determined by stability, maintenance, repairs or upgrades such as safety or cybersecurity modifications and highlighting that these can be necessary during the expected lifetime.

These three guidance documents indicate that manufacturers are to define an expected lifetime for devices.

Standards

Standards provide routes of conformity for manufacturers within the overall regulatory framework. These can be helpful as evidence of conformity or presumption of conformity in some circumstances.

EN ISO 20417[5] defines expected lifetime and expected service life as the time-period specified by the manufacturer during which the medical device or accessory remains safe and effective for use.

---

[2] MDCG 2022-21 - Guidance on Periodic Safety Update Report (PSUR) according to Regulation (EU) 2017/745 - December 2022

[3] MDCG 2020-8 Post-market clinical follow-up (PMCF) Evaluation Report Template A guide for manufacturers and notified bodies

[4] IMDRF Technical document; Essential Principles of Safety and Performance of Medical Devices and IVD Medical Devices

[5] EN ISO 20417:2021 Medical devices — Information to be supplied by the manufacturer

The definitions are based on the definition for 'expected service life' in EN/IEC 60601-1[6] and added notes. One note points out that some medical devices have an absolute lifetime (for example, years of service or number of uses), whereas other medical devices (for example, software) may have a relative lifetime based upon other components needed for intended use or time between releases.

Another note remarks that it is up to the manufacturer to define the expected lifetime of their medical device. Since the risk management process requires the manufacturer to verify the effectiveness of all risk control measures, the manufacturer needs to assess the effectiveness of risk control measures for the entire expected lifetime (or there could be an unacceptable risk).

A third note reminds that information for use should be provided related to activities that are required to be performed during the lifetime of the medical device for preventive maintenance, tests and to identify the approaching end of life of the device i.e before the device reaches that state.

Manufacturers are required to continue to perform post-production surveillance and ensure that their medical device remains safe (for example, by providing security updates during that expected lifetime).

EN/IEC 60601-1 with scope for medical electrical equipment and systems defines expected service life in a similar manner to the IMDRF definition of expected lifetime or expected service life, as the time period specified by the manufacturer during which the medical equipment or system is expected to remain safe for use to maintain basic safety and essential performance where maintenance can be necessary and with additional information relating to provision of expected service life in the risk management file. The reference to risk management file therefore implies that the manufacturer is using the framework of EN ISO 14971[7] and general and safety performance requirements of the regulations (MDR 2017/745). The subclause goes further with the definition where expected service life is the time period in which the suitability for intended use is relevant and during which all risk control measures reman effective to ensure risks remain acceptable as part of the risk management process with reference to clauses 4.5 (alternative risk control measures or test methods), 4.7 (single fault conditions), 7.1.3 (durability of markings), 8.6.3 (protective earthing of moving parts), 9.8.2 (tensile safety factor), and 11.6.6 (cleaning and disinfection).

---

[6] EN/IEC 60601-1:2005+AMD1:2012/ IEC 60601-1:2005+AMD1+AMD2:2020 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance

[7] EN ISO 14971:2019 Medical devices — Application of risk management to medical devices

control measures reman effective to ensure risks remain acceptable as part of the risk management process with reference to clauses 4.5 (alternative risk control measures or test methods), 4.7 (single fault conditions), 7.1.3 (durability of markings), 8.6.3 (protective earthing of moving parts), 9.8.2 (tensile safety factor), and 11.6.6 (cleaning and disinfection). It also requires the manufacturer to provide information to responsible organisations (within instructions for use) for them to assess when a device is approaching the end of life in terms of years of service or number of uses which could additionally include tests as part of maintenance or other criteria as addressed as part of the manufacturers risk management process.

Whilst EN/IEC 60601-1 subclause 4.4 for the definition of expected service life includes assumptions relating to responsible organisations following manufacturers' instructions for routine maintenance, it should be carefully considered that information for use does not necessarily reduce risks. For example, risk to the patient, and criteria for assessment of the medical device should be of indications prior to the device having reached end of life. Characteristics, such as, for example increased temperature, cracking and significant performance changes would indicate that the end of expected lifetime would already have been reached. It should also be noted that the frequency of service or maintenance activities should not be confused with full lifetime of a device since devices are replaced for continued intended use on the market after service and repair activities and that safety and performance for intended use should be maintained until end of lifecycle and disposal.

Other standards which are notable for defining device lifetime, include EN ISO 17664[8] for processing of healthcare products (critical, semi-critical and non-critical medical devices). Clause 5 of EN ISO 17664-1 details risk analysis relevant for the lifecycle of the medical device and necessary maintenance. In defining expected service life the responsible organisation should be assumed to follow manufacturers' instructions for routine maintenance within the risk management framework and process of EN ISO 14971 which details characteristics of nature and design of the medical device, contamination, intended use, lifecycle, foreseeable user error and misuse, user training, equipment required for processing, accessories and consumables for processing, maintenance of the device, post market information, limitation on number of reuses and necessary warnings. For these devices the standard is more explicitly listing characteristics for the device and has relevance to usability and therefore to application of EN/IEC 62366[9].

[8] EN ISO 17664-1:2021 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 1: Critical and semi-critical medical devices and ISO 17664-2:2021 Processing of health care products — Information to be provided by the medical device manufacturer for the processing of medical devices — Part 2: Non-critical medical devices

[9] EN/IEC 62366-1:2015+A1:2020 Medical devices. Application of usability engineering to medical devices

EN ISO 14630[10] for non-active surgical implants, includes requirements (clause 4) relating to intended performance, whereby the manufacturer is required to determine in the technical documentation, functional characteristics and intended lifetime of the device.

This may be with relevance to published documents such as literature and standards for device safety. For an example of a coronary stent with defined lifetime of 10 years the consideration of intended performance may translate to long term performance and PMS or PMCF follow-up over the devices intended lifetime.

Consideration of different device types

The considerations for device lifetime for safe and effective use may considerably vary according to the device type and individual devices characteristics for performance and safety, and effects of biological actions and deterioration during a device lifetime. For example, the lifetime of a scalpel and its characteristics for safety would vary to an active device with wear components, to software only devices and to devices which are implantable and more highly susceptible to not only mechanical stresses but also biological actions.

It should also be noted that the frequency of service or maintenance activities not to be confused with full lifetime of a device since devices are replaced for continued intended use on the market after service, repair or maintenance activities and that safety and performance for intended safe and effective use should be maintained until end of lifecycle and disposal under the framework of EN ISO 14971.

Lifetime may be considered as the time span from the point of first use to disposal and in terms of lifetime in use (lifetime with the patient or user) and functional use within the product lifecycle from conception through design and manufacture, shelf-life duration, lifetime in use and functional life to decommission and disposal.

A finite lifetime needs to be defined even for capital goods devices where components may be replaced to prolong the device through service maintenance. Similarly for software devices, whilst software has no physical component which could deteriorate, operating platform updates will inevitably be required and upgrades, for instance to add new cybersecurity measures likely to be needed, to maintain device safety and usability.

[10] ISO 14630:2012 Non-active surgical implants — General requirements

Implantable devices have differing issues; including that many may be in the body longer than their device lifetime in terms of claimed lifetime to state of the art (SOTA) and there can be risks relating to the stage of the device life in terms of degradation and deterioration. For example, a coronary stent may have a lifetime of 10 years, but if implanted in a young patient who lives a long lifetime the 10 years may be exceeded and therefore additional technical data may be needed to confirm safety or monitoring in post market phase. For those devices with biological characteristics whereby the lifetime differs to stage of biological actions, rate of reaction and absorption to the body may be factors to be considered to steady state or removal.

For legacy devices, where the device has already been designed and been in use the manufacturer may have already defined or have available supportive information from post-production phase.

Since different device types may have significant differences to their characteristics some generalised examples are given below.

Active devices

Typical device lifetime provided in years (or uses) corresponding to reasonable risk for failure modes of the device and their severity.

Typical analysis relevant for safe and effective use may include the following as part of evaluation and risk management process using standards appropriate for the device, whereby it is expected that the manufacturer reduces probability/risk of failure as far as possible and no unacceptable risk to patient or user exists during the lifetime of the device with residual risks and lifetime made available to users through the device instructions for use;

- Characteristics of the device including any shelf life.
- Component/material analyses including any failures occurring between service and maintenance activities within the declared lifetime of the device.
- Statistical determination based on single fault safety and reasonably foreseeable misuse and other usability factors (e.g. mean time before failure (MTBF) with confidence and reliability intervals, Weibull distribution).
- Maintenance activities determined throughout lifecycle (e.g. servicing frequency, part replacement schedule, functional and safety tests).
- Consideration of usability of the device and maintenance activities.
- Verification and validation (e.g. Wear testing, corrosion testing, accelerated aging (HALT/HASS), functional safety analyses).
- Post market phase (e.g. length of follow-up duration for clinical endpoints).
  See also below clinical data and statistical analysis

For some devices, reasonably foreseeable misuse in the context of risk management and usability may need to be considered in the post market phase due to continued use by healthcare organisations beyond service interval and in relation to state of the art since healthcare institutions may continue to use available devices.

Software devices

For medical device software (MDSW), a statement of the device lifetime along with a plan for how the following will be managed would be expected with residual risks and lifetime made available to users through the device instructions for use;

- Changes to the software.
- The end of life of any operating system platforms or tools on which the device or its manufacture is based.
- Changes and obsolescence to software items including software of unknown provenance (SOUP).
- Maintenance of security, compatibility, and operability for intended performance and use where the full device or device-system combination being safe for intended use including with use of artificial intelligence algorithms.
- Continued demonstration of state of the art, for example to the technology which the software uses.

Implantable devices

Implantable devices include surgically implanted devices in the body.

Consideration of safety for the full implanted life of the device must be considered. While a device may only have a ten-year performance specification, it is expected that safety would be considered for the duration of the implantation.

Implantable devices are present in body until removed where that is possible, which may be longer than the claimed device performance lifetime to SOTA.

Typical device lifetime provided in years corresponding to reasonable risk for failure modes of the device and their severity.

Typical analysis relevant for safe and effective use may include the following as part of evaluation and risk management process using standards appropriate for the device, whereby it is expected that the manufacturer reduces probability/risk of failure as far as possible and have no unacceptable risk to patient or user during lifetime of the device with residual risks and lifetime made available to users through the device instructions for use;

- Characteristics of the device (e.g. sterile, reusable, length of time the device will stay in place, shelf life).
- Component/material analysis (e.g. parameters affecting lifetime eg. exposure, distance travelled).
- Pre-clinical data (e.g. functional testing, wear and corrosion, mechanical loading, biocompatibility).
- Time to reaching steady state, time during which an implant is functional, time limited period of intended use (for example fracture fixation devices).
- The lifetime of the power source of active implantable medical devices.
- Usability (e.g. user needs met for intended lifetime and safety for devices left inside the body).
- Post market phase (e.g. length of follow-up duration for clinical endpoints).

See also below clinical data and statistical analysis

Biological devices

For those devices which include for example, a medicinal product, or have an ancillary pharmacological, immunological, or metabolic mode of action there may be a different situation concerning device performance lifetime. These devices may for instance include substances or materials which are present in body until removed, e.g. through absorption and excretion.

Typical device lifetime provided corresponding to reasonable risk for failure modes of the device and their severity.

Typical analysis relevant for safe and effective use may include the following as part of evaluation and risk management process using standards appropriate for the device, whereby it is expected that the manufacturer should reduce probability/risk of failure as far as possible and no unacceptable risk to patient or user during lifetime of the device with residual risks and lifetime made available to users through the device instructions for use;

- Characteristics of the device including shelf life.
- Rate of action, absorption and reach of steady state for materials or substances.
- Determination of functional lifetime (e.g. vascular closure, suture prior to absorption, tissue scaffold).
- Mechanical integrity until clinically cleared or absorbed (e.g. for as long as you can detect material, cell mediated remodelling, material digestion, gold standard methods).
- Risk analyses and benefit risk (e.g. effects of latter stages, inflammation, end of steady state as relevant to material properties and characteristics).

- Post market phase (e.g. length of follow-up duration for clinical endpoints).
  See also below clinical data and statistical analysis

Clinical Data

Annex XIV part B is clear that manufacturers are expected to ensure that activities of post market clinical follow up (PMCF) are continued to ensure that clinical data is collected to sufficiently support the claimed lifetime of the device. Standard of care devices (MDCG 2020-6[11]) and well-established technologies may have sufficient clinical evidence.

The manufacturer's PMCF plan is expected to ensure general, and when appropriate specific activities are performed to understand the safety and performance of the device throughout the expected lifetime.

In the case of implantable or class III devices it would be expected that specific PMCF activities are planned to ensure that close follow up of the device is performed with clear safety and performance objectives to identify new or emerging risks or performance concerns that may become evident in the later lifetime of the device. When sufficient data has been collected over the lifetime, and the longer-term safety and performance is known, then it may be possible where general activities of PMCF become sufficient; a justification could be provided for not conducting specific PMCF for well-established technologies listed in Article 61.6(b) of the MDR, and for standard of care devices for which common features defined in section 1.2 of the MDCG 2020-6 guidance document if the data provided by the manufacturer is sufficient to support the expected lifetime of the device under evaluation.

Article 86 also expects that the main findings of the PMCF activities are reported within the periodic safety update report (PSUR).

The Guidance MDCG 2022-21[2] includes requirements for periodic safety update report and device lifetime is considered part of the core aspects of clinical evaluation plans and reports and must be declared and supported through technical documentation and clinical data.

Post market plans are relevant for all medical devices and where there are questions related to safety and effectiveness for intended use post market clinical follow-up (PMCF) is specified by manufacturers including for those devices with novelty.

PMS data is a tool which manufacturers may use to review device performance for intended use within the regulatory framework.

[11]MDCG 2020-6 Regulation (EU) 2017/745: Clinical evidence needed for medical devices previously CE marked under Directives 93/42/EEC or 90/385/EEC A guide for manufacturers and notified bodies April 2020

The clinical, usability and regulatory framework also considers the device information for safety as part of the risk management and usability engineering processes.

Manufacturers are expected to continue to monitor and collate clinical data for safety and extend device lifetime (if applicable) based on the clinical data including literature for intended use.

Statistical Analysis

The most common statistical methods include those that look at mean time before failure and reliability (including Weibull analyses, HALT, HASS aging analysis)

Post market surveillance analysis of field data may also be used by manufacturers for the duration that the device has been placed on the market, for devices to which equivalence is claimed and where reliable maintenance data is available. Statistical methods must be reasonable, and it should be noted that absence of evidence is not itself evidence of absence.

Manufacturers may determine rates of failure and rationales for use of data and statistical methods employed. Where sample numbers are based on analysis of the test method validation, the rationale used should consider; repeatability and reliability of the test method, the quantitative and non-quantitative variables taken into account alongside consideration of what the percentage failure means for the device type. Any rationale is recommended to correspond to reasonable risk of severity and likelihood of failure modes for the device and SOTA and lowest level of device lifetime used.

Recommendations

Team-NB recommendations are outlined below:

- Manufacturers are expected to define the time period for lifetime or expected lifetime, or expected service life in technical documentation and made available to the user through instructions for use. This should be defined in terms of all applicable characteristics relating specifically to their device. This definition should consider safe and effective use through the useful life, for the device's entire lifecycle, and in terms for SOTA in accordance with the Medical Device Regulation 2017/745 and available guidance. Standards are also tools for use. The relevance to be applied (where applicable) to when the device is removed from the body even if that time would exceed the currently available state of the art.

- Unlimited lifetime or undefined lifetime is practically impossible to claim and lifetime is expected to be defined in quantitative terms of number of years, number/intensity of uses, or operational period, to the requirements of applicable standards (for example, such as MDCG 2020-7[12] and ISO 17664-1[8]) and where other additional tests are required such as functional testing are required that they are confirmed dependent on typical use.

- Manufacturers are expected to incorporate device lifetime as part of design inputs where possible for non-legacy devices, and to include testing and acceptance criteria as part of design outputs and functional verification testing and analysis for the device thereby incorporating lifetime into the design and design processes. Clear identification as to how each element of total device lifetime has been verified with the supporting evidence's for a realistic basis for normal conditions of use, considering single fault safety and reasonably foreseeable misuse, especially for legacy devices where design has already been completed is expected.

- Clinical data sources could be used as supportive evidence to the lifetime of the device from post market surveillance, post market clinical follow up activities and PSUR throughout the lifetime of the device in consideration of applicable guidance such as MDCG 2022-21[2] where applicable. The device performance and safety profile to be demonstrated throughout expected lifetime where characteristics and performance must not change negatively during the device in such a manner that unacceptable hazards could arise, and positive benefit risk profile is maintained together with acceptability of risks over the device lifetime.

- Where no clinical study data is available, data from literature, or whether a PMCF study is required as well as applicable device characteristics and pre-clinical performance evaluation which include device stages of use such as rate of reaction, absorption, HALT/HASS testing, information for safety, functional use, and impact to benefit risk ratio could be considered.

- Manufacturers may provide justifications for their devices specifically for their device or testing and analysis methods to be considered on an individual basis as part of conformity assessment. Any such justification should correspond to reasonable risk of severity and likelihood of failure modes for the device and SOTA irrespective of procedures and take into consideration how long the device is reasonably likely to be safe and effective for use and of the duration in the body (where applicable) to decommission

[12] MDCG 2020-7 Post-market clinical follow-up (PMCF) Plan Template A guide for manufacturers and notified bodies, April 2020

Conclusions

The regulations and guidance refer to lifetime of a medical device in terms of safe and effective use. This is very broad and there are substantial differences between different device types in terms of their characteristics for intended use, and aspects taken into account by manufacturers in specification of the lifetime of their devices. It is recommended that manufacturers specification should correspond to reasonable risk of severity and likelihood of failure modes for the device, consist of pre-clinical performance testing and clinical data or data from clinical data sources such as PMCF studies for benefit risk determination within ISO 14971 risk management process. The service interval should not be confused with device lifetime or expected service life to decommissioning or removal from the body or steady state, as applicable to the device. The indication of years of use or number of uses avoids ambiguity in the conformity assessment process for confirmation of applicable supporting evidence for device lifetime.