GMED LNE GROUP Newsletter

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SAFETY AND PERFORMANCE OF NON-ACTIVE IMPLANTS: HOW TO MEET THE PRECLINICAL REQUIREMENTS OF REGULATION (EU) 2017/745?

Demonstrating the safety and performance of non-active surgical implants relies on rigorous preclinical data, guided by constantly evolving standards and guidelines. The 2024 version of ISO 14630 and the 2025 Team-NB best practices provide key details for compiling technical documentation in accordance with Regulation (EU) 2017/745.

This newsletter aims to help manufacturers understand and structure the preclinical data to be included in their technical documentation. It explains what data are expected, how tests should be conducted, what justifications are required and the specificities related to devices used in combination or to the demonstration of stability.

A WHAT ARE PRECLINICAL DATA?

Preclinical data demonstrate the implant's safety and intended performance by simulating the intended conditions of use. The technical documentation must include the results and critical analyses of all verifications, tests, and/or studies carried out to demonstrate compliance with the requirements of Regulation (EU) 2017/745, particularly with the applicable general safety and performance requirements (GSPR). Below are typical preclinical data used to assess the risks identified in the risk analysis or to substantiate claimed performance.

PRECLINICAL DATA	RECOMMENDATIONS
Engineering tests, laboratory tests, simulated use testing, design calculations	Provide and justify Detailed test conditions for any tests.
Animal, in vitro, ex vivo, cadaveric, or simulated cadaveric evaluations	Detail objectives, methodology, results, analyses and conclusions, including justification and limitations of the chosen model(s). For in vitro tests, justify the model selection (e.g., Sawbones).
Mechanical, physical, chemical, and microbiological characterization	Identify relevant standards listed in the bibliography of ISO 14630:2024.
Static and/or dynamic load testing	
Reliability, wear, corrosion, and friction corrosion tests	ISO 16429 standard can be used to assess corrosion resistance.
Suitability of implant dimensions and shape for the target population	Demonstrate for the target population (GSPR14.2(a)).
Biological evaluation	Structure the biological evaluation report per ISO 10993 1 where applicable.
Electromagnetic compatibility	The manufacturer must determine safety of the implant in the magnetic resonance environment. Safety is defined as the absence of unacceptable risk. The following documents can be used to assess compatibility with the MRI environment: ASTM F2503, ASTM F2052, ASTM F2119, ASTM F2182, ASTM F2213.
Usability engineering	The usability engineering file may follow IEC 62366 1.
Justification/Evidence of conformity and/or safety based on published scientific and technical literature	It is recommended to present the search strategy (keywords and databases), the criteria for selecting articles, and the selected articles.

B WHAT INFORMATION MUST BE PROVIDED FOR A TEST?

It is advisable to include a table summarizing all preclinical data and, where useful, the source that triggered each item (e.g., an identified risk, a regulatory requirement, or a claimed performance). The technical documentation should include the following for each preclinical test:

a) → Test conditions
Some test methods are listed in the ISO 14630:2024 bibliography. If a test was performed to a standard that has since been amended, an analysis of the impact of the amendments must be provided and, if necessary, additional tests must be performed. For certain standards, (e.g. ISO 10993-17:2023 (§5.1.1), ISO 21535:2024 (§ 5.1) and ISO 21536:2023 (§5.1)), provisions address tests performed to a previous version.
Where tests were not been performed per the applicable standards or reference documents, the manufacturer must demonstrate that the chosen method is equivalent.

Test conditions may be defined and justified on the basis of scientific/clinical literature, relevant post-market information, guidelines, state of the art, simulations, etc. In all cases, test conditions shall simulate intended conditions of use, including the implant's lifetime. All preparatory steps undertaken before testing shall be fully documented in the test report.

b) → Characteristic/specification to be verified/validated
The manufacturer must specify the characteristic or parameter being tested and substantiate its connection to the applicable technical, performance, or safety specifications.

c) → Acceptance requirements/criteria and their justification
The manufacturer must define and justify the acceptance criteria, as measurable interpretation of specifications, enabling conformity assessment of the implant. criteria may be based on technical calculations, relevant scientific literature, standards, guidelines, etc. They may also be derived from the performance of a reference or demonstrably similar CE marked implant tested under the same conditions as the subject implant, in line with ISO 14630:2024. In that case, the manufacturer must compare the two implants per the elements defined in the standard.

d) → Laboratory identification (name and address)
The laboratory responsible for conducting the test, internal or external, must be clearly identified by its name and address. All raw data and the completion date of the test must be provided in the technical documentation.

e) → Evidence of the laboratory competence
The manufacturer must provide evidence that the laboratory is competent to perform the test and to produce reliable results. This evidence may take the form of an ISO 17025 certificate covering the relevant type of test at the time it was performed. It may also consist of a body of documentation demonstrating laboratory competence, including staff qualifications, calibration of equipment and facilities, established quality procedures, and validation of the test methods used.

f) → Representativeness of the sample tested
The tested sample must be clearly identified. Its representativeness with respect to the implant to be CE marked must be demonstrated, taking into account product variants, design, and the manufacturing process. The differences between implants must be analyzed in order to assess their impact on test results. If several tests have been performed for the same characteristic, a diagram or accompanying explanation shall illustrate how the studies were conducted and demonstrate how the requirements were met. A 'worst case' implant may also be identified through simulation.

If the tests were performed on a prototype, a previous generation of the implant, or any non-representative version of the finished product, justification for the sample's representativeness must be provided.

The characteristics and performance requirements shall be demonstrated while considering the impact of manufacturing processes on material properties (GSPR 10.1). Steps such as cleaning, sterilization, welding, laser marking, reworking, packaging, shipping, and storage conditions, etc. may affect the demonstration of the implant's safety and performance.

For example, if a device is intended to be supplied sterile, testing must be conducted on a sterile device, or appropriate justification must be provided otherwise. The maximum sterilization dose and the number of sterilization cycles must also be taken into account.

The justification for the sample size may be based on risk analysis, if applicable.

g) → Conclusion on the conformity of the implant
The manufacturer must critically analyze the test results to determine whether they meet the acceptance criteria; and the statistical inferences must be clearly demonstrated. All deviations from the protocol shall be fully documented in the reports, with justification supporting their acceptability.

C IS TESTING SYSTEMATICALLY REQUIRED?

If no test was performed, the technical documentation must explain why. In some cases, intended safety and performance may be justified by a detailed scientific/technical rationale.

D WHAT PRECLINICAL DATA IS REQUIRED FOR DEVICES USED IN COMBINATION WITH OTHER DEVICES?

For an implant intended to be used with other devices or equipment, the combination must be safe and must not compromise the intended performance (GSPR 14.1). The manufacturer must therefore demonstrate that the implant complies with the GSPR when connected to the device(s) used in combination. For example, for a femoral head, the devices used in combination include the femoral stem and acetabular cup in total hip arthroplasty., instruments connected to an implant during placement are also considered combination devices. Any applicable restrictions on use for these combinations must be clearly indicated on the label and/or in the instructions for use.

E HOW TO DEMONSTRATE "STABILITY, INCLUDING SHELF LIFE"?

Stability must be demonstrated throughout the shelf life and the lifetime of the implant, as specified by the manufacturer.

ISO 14630:2024 specifies preclinical data to substantiate the use-by date.

Shelf life is the period between batch release and the use-by date. Devices must be designed, manufactured, and packaged so that their characteristics and performance are not impaired during transport and storage (e.g.by temperature and humidity fluctuations (GSPR 7)).

Lifetime of an implant is the period, specified by the manufacturer, during which the implant's characteristics and performance are not impaired to a degree that endangers patient/user health or safety under normal use conditions. Lifetime starts at the date of implantation and can be viewed as:
- Functional lifetime: period during which the implant maintains characteristics and performance under normal use; safety and intended performance must be demonstrated throughout this period.
- Implantation duration: period from implantation to removal, or until completely resorption or excretion. Implant safety must be demonstrated throughout this period.

Example: osteosynthesis devices are intended to stabilize fractures by maintaining bone fragments in position during healing (functional lifetime). Depending on the material, they may remain implanted for the patient's entire life or gradually resorb (implantation duration).

Where preclinical data do not cover the entire lifetime, clinical data should complete the demonstration.

Conclusion

High quality, rigorous preclinical data are essential to demonstrate the safety and performance of non-active surgical implants, in line Regulation (EU) 2017/745. Leveraging updated references such as ISO 14630:2024 and Team-NB best practices enables manufacturers to structure technical documentation in a consistent, comprehensive, and compliant manner.

Beyond regulatory compliance, a structured approach to preclinical data facilitates exchanges with notified bodies, anticipates expectations during assessment strengthens the overall consistency of technical documentation and secures the steps involved in bringing products to market.

Sources :
- *Regulation (EU) 2017/745*
- *ISO 14630:2024*
- *Team NB Position Paper on BPG for the Submission of TD under Annex II and III of MDR (EU) 2017/745 V3*
- *Team-NB Position Paper: Medical Device Lifetime*

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Choose GMED

WHY CHOOSE GMED FOR THE CERTIFICATION OF YOUR NON-ACTIVE SURGICAL IMPLANTS?

GMED relies on recognized expertise in the evaluation of non-active implants and a deep understanding of the requirements of Regulation (EU) 2017/745. Our technical teams apply state of the art standards, including ISO 14630:2024, as well as Team-NB best practices, ensuring a harmonized and consistent interpretation of regulatory expectations.

GMED is your trusted Notified Body for securing market access for your medical devices.

To go further

TRAININGS FOR AMERICAN REGION

European Medical Device Regulation (EU) 2017/745
2-day training session | Virtual Classroom
→ REGISTER FOR THE UPCOMING TRAINING

European in Vitro Diagnostic Device Regulation (EU) 2017/746
2-day training session | Virtual Classroom
→ REGISTER FOR THE UPCOMING TRAINING

Systematic Literature Review for Medical Devices
1-day training session | Virtual Classroom
→ REGISTER FOR THE UPCOMING TRAINING

The Clinical Evaluation Report (CER) Requirements Under the EU MDR 2017/745
1-day training session | Virtual Classroom
→ REGISTER FOR THE UPCOMING TRAINING

Medical Device Electrical Safety
2-day training session | Virtual Classroom
→ REGISTER FOR THE UPCOMING TRAINING

Biocompatibility of Medical Devices
2-day training session | Virtual Classroom
→ REGISTER FOR THE UPCOMING TRAINING

TRAININGS FOR OTHER REGIONS

Conduct a biological evaluation of medical devices
SA21B | 2-day training session | On demand

Prepare a usability engineering file for medical devices
SA49 | 2-day training session | On demand

Adapt your quality management system to the ISO 13485 v2016 standard
SA19 | 2-day training session | On demand

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