G-420_03E_GROUPING AND COMBINATION OF MEDICAL DEVICES WITHIN A SINGLE TECHNICAL DOCUMENTATION FILE

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Guidance Document: Grouping and Combination of Medical Devices within a single Technical Documentation file

Issued by:

Head of Notified Body
DQS Medizinprodukte GmbH

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Regulatory Basis:

Regulation (EU) 2017/745 on Medical Devices (MDR)

Disclaimer:

This document is not legally binding; rather, it reflects the interpretation and expectations commonly applied by DQS Medizinprodukte GmbH as a Notified Body when assessing manufacturer submissions.

1 Purpose and scope

The purpose of this guidance is to clarify how manufacturers may combine multiple medical devices into a single Technical Documentation (TD) file under MDR 2017/745, and under what conditions devices may be grouped while maintaining conformity with Annex II and Annex III requirements.

This guidance applies to:

- Stand-alone devices
- Device variants and configurations
- Device families / product ranges
- Systems or procedure packs (where applicable)
- Accessories intended to be used with a parent device

2 General principles for bundling devices in a single TD

Under MDR 2017/745, a single Technical Documentation file may cover a group of devices only if the devices are sufficiently similar so that:

1. The same conformity assessment route applies,
2. The same General Safety and Performance Requirements (GSPR) checklist is valid with only minor variations,
3. The same risk management file (RMF) structurally applies,
4. The same intended purpose and functional principle are shared or clearly linked,
5. The verification and validation (V&V) strategy is aligned across the devices.

The Notified Body must be able to assess the group as a coherent whole without risking omission of device-specific risks or performance claims.

3 Acceptable degrees of device variation

The following sections describe the degree of allowable variation to still fall within one TD.

3.1 Device family concept

A group of devices may be considered a “family” when they share:

- Same risk class (per Annex VIII)
- Same intended purpose (differences only in magnitude, range, or patient population)
- Same essential design and manufacturing process
- Same underlying technological principle
- Same clinical evaluation strategy

Permissible variations in a device family may include:

- Sizes (e.g., surgical implants differing only in diameter or length)
- Minor material variations (e.g., different coating colors, provided biocompatibility impact is addressed)
- Accessory options that do not alter the parent device's function
- Configurations or usability features that do not change risk profile

Non-permissible variations include:

- Different mechanism of action
- Substantial material changes affecting biological safety
- Different technological principles (e.g., mechanical vs. electrical)
- Different intended purposes or medical indications
- Different sterilization methods if they introduce significantly different risks

3.2 Device variants

Variants may be grouped if each variant is traceable to a common core design.

A single TD may include variants if:

- The risk analysis covers variant-specific hazards
- V&V testing includes worst-case variant selection
- Labelling differences are managed in a controlled and documented manner

Variants should not be grouped if:

- They introduce new risks that are not addressed by the shared RMF
- The worst-case selection becomes unclear or unrealistic
- They require separate clinical evaluations

3.3 Accessories

Accessories may be included in the parent device's TD only if:

- They are intended exclusively for use with that device
- Their performance characteristics do not introduce independent clinical risks
- Their conformity assessment relies on that of the parent device

Accessories that function as stand-alone devices (e.g., active power units, software, measurement systems) must either have dedicated TDs or clearly segregated sections within a combined file.

4 Systems, Procedure Packs, and Device combinations

A single TD may be acceptable for system configurations or procedure packs when:

- The manufacturer is responsible for integration
- Essential performance relies on combined operation
- A unified RMF addresses both individual and interaction risks

However, where individual components have independent intended purposes, risk classifications, or regulatory obligations, separate TDs are generally required, even if presented in a structured, cross-referenced dossier set.

5 Practical criteria for accepting a single TD

The Notified Body typically applies the following criteria when determining suitability of bundling:

Devices should demonstrate high similarity in:

- Risk Class – identical
- Intended Purpose – shared or directly linked
- Design Architecture – ≥80% identical core design
- Technological Principle – same fundamental technology
- Manufacturing Processes – same production flow and quality controls
- Materials – identical or minor variants justified in RMF
- Sterilization – identical method and validation approach
- Clinical Evidence Set – common clinical rationale or datasets
- V&V Strategy – shared plan with clear worst-case rationale

If a device group fails multiple criteria above, the Notified Body will require separate TDs.

6 Recommendations for Manufacturers

To facilitate successful NB review:

- Clearly justify the grouping rationale in the TD introduction section
- Provide a device family or variant map that highlights similarities and differences
- Define worst-case testing logic early and transparently
- Maintain unambiguous labelling traceability
- Use modular TD structures enabling future expansion

A well-structured, modular TD significantly reduces review time and prevents iterative questions.

7 Final remarks from the Head of the Notified Body

As a Notified Body, our objective is to ensure patient safety and regulatory compliance while enabling efficient review processes. When devices are meaningfully similar in design, purpose, risk, and technology, bundling into a single Technical Documentation file is not only permissible but often beneficial for both manufacturers and regulators.

However, when the Technical Documentation becomes too complex due to the amount of devices covered, similarity becomes insufficient, or when risks diverge, separate documentation is essential to ensure MDR compliance and robust demonstration of safety and performance.

At the end, the final decision of the Notified Body depends also on the quality and structure of the Technical Documentation established by the manufacturer who needs to provide the information in a clear, organized, readily searchable and unambiguous manner.

Notified Body pricing for the assessment of Technical Documentation does also take into account the complexity of the Technical Documentation and the devices covered by it. Therefore, pricing must not be considered by the manufacturer as a factor when deciding which devices to be grouped in a single Technical Documentation or not.

It should also be noted that the likelihood of certification delays increases with the complexity of the Technical Documentation. Devices can only be added to a CE certificate when all issues for all devices covered by the Technical Documentation are resolved.

Manufacturers are encouraged to consult with us early whenever uncertainty exists regarding grouping strategies.

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DQS Medizinprodukte GmbH	DQS Medizinprodukte GmbH

Appendix A.1 – Bone plates as an example: Device-specific considerations

Bone plates share a generic intended purpose — internal fixation/stabilization of fractures — and typically share the same technological principle (rigid fixation using metal plate and screws). That supports grouping in principle. However, the anatomical site affects:

- **Mechanical loading / functional requirements.** Load magnitude and fatigue life differ widely (e.g., distal radius vs femur). Plates intended for high-load, weight-bearing long bones may require different mechanical testing (fatigue, fracture toughness) and possibly different design features (locking vs non-locking, thickness, cross-section).
- **Design geometry and size ranges.** Plate geometry (contour, hole spacing), thickness and screw size vary — may create different worst-case behaviours.
- **Materials & surface treatments.** Different coatings or alloy variants (e.g., Ti vs stainless steel, anodising/coatings) change biocompatibility, corrosion and mechanical behaviour.
- **Sterilization and packaging differences.** Some plates may be supplied sterile; others non-sterile. Sterilization method/validation may create divergent evidence needs.
- **Clinical performance expectations.** Healing times and clinical outcome claims can differ by site/population; clinical evidence must support each claim or show equivalence.

If these site-driven factors change the risk or performance profile, they become a reason not to bundle. (Illustration: grouping femoral load-bearing long-bone plates with small facial plates would usually be inappropriate.)

Appendix A.2 – Bone plates as an example: Decision checklist

Use this as a pass/fail checklist. All of the following should be true (or justified) to support a single TD grouping:

- Same intended purpose (internal fixation) and same mode of action across plates.
- Same risk class (or documented rationale why risk class can be considered equivalent for the family). If classification differs, do not combine.
- Shared core technological principle and core design architecture (metal plate and screw fixation; same locking principle or clearly variant-managed).
- Materials / coatings are identical or differences are justified with biocompatibility and corrosion data in the TD.
- A single Risk Management File (RMF) can cover shared hazards, with annexes for site-specific hazards; worst-case hazards are identified and mitigations show coverage for the whole family.
- A single V&V strategy is feasible using a clear worst-case selection (e.g., largest dimension and highest anticipated load represent worst-case fatigue). All other variants are covered by justification or targeted tests. Test reports must be traceable to the variants.
- Clinical evaluation (CER) either covers all variants or provides variant-specific annexes that justify equivalence. If clinical performance differs substantially by site, separate CERs (and TDs) may be needed.
- Labelling/IFU differences are manageable via variant-specific IFUs within the TD (not requiring separate TD structures).

- Post-market surveillance/PSUR mapping: manufacturer can show how PSUR and PMS cover the family or justify separate reports for specific Basic UDI-DIs if necessary.

If you can answer yes and provide documentary justification for each point, bundling is a defensible approach. If you answer no on one or more critical items (classification, clinical evidence, worst-case V&V, or materials), you should plan separate TDs.

Appendix A.3 – Bone plates as an example: Practical worst-case / sampling strategy

When grouping bone plates, explicitly document the worst-case rationale:

- **Mechanical testing worst cases:** choose the plate geometry and size expected to generate highest stress and lowest fatigue life (e.g., longest span with smallest cross-section) and test that for static strength, fatigue, torsion. Show why smaller/less stressed plates are encompassed.
- **Materials worst case:** if multiple alloys/coatings are used, identify the material with the highest risk (e.g., new coating) and provide biocompatibility and corrosion testing; if materials differ materially, include separate biocompatibility annexes.
- **Sterilization worst case:** if some variants are sterile, test the sterilized configuration for packaging integrity and function; document non-sterile variants separately.
- **Usability/IFU worst case:** perform usability testing for the most complex surgical procedure / site and justify applicability to less complex sites.
- **Other worst cases:**

Document the sampling and rationale in the TD and be ready to justify the choices to the Notified Body during assessment per MDCG sampling guidance.

Appendix A.4 – Bone plates as an example: UDI, Basic UDI-DI and DoC implications

Basic UDI-DI assignment: you may assign a Basic UDI-DI to the device family if the family is justified. If certain variants need their own Basic UDI-DI (different marketed devices with distinct essential characteristics), reflect that in the TD and EUDAMED registration.

Declaration of Conformity (DoC): A DoC may reference more than one Basic UDI-DI if the manufacturer justifies grouping per Annex IV and MDCG guidance. Ensure the DoC and the TD clearly map Basic UDI-DI to the device variants and their UDI-DIs.

Appendix A.5 – Bone plates as an example: TD structure considerations

Use the grouped TD template you already have, but be explicit about the following annexes for bone-plate families:

- Family overview — explain anatomical sites covered and rationale for grouping.
- Variant matrix — list each plate model, size range, Basic UDI-DI(s), material, intended anatomical site, packaging/sterility status, and other variations.
- RMF (shared) + site-specific appendices — include worst-case justifications.
- V&V shared reports + per-variant evidence annexes — mechanical testing, biocompatibility, sterilization validation, packaging.
- Clinical evaluation — shared CER with variant-specific annexes or separate CERs where needed.
- Traceability matrix mapping each Basic UDI-DI to GSPRs, RMF, V&V and CER references

Appendix B – Key references

- Regulation (EU) 2017/745 (MDR)
- MDCG 2019-13:2024 – Guidance on sampling of MDR Class IIa / Class IIb devices for the assessment of the Technical Documentation
- MDCG 2022-7:2022 – Q&A on the UDI system under Regulation (EU) 2017/745
- MDCG 2022-21:2022 – Guidance on PSURs according to Regulation (EU) 2017/745
- Team-NB Position Paper:2022 – Best Practice Guidance for the Submission of Technical Documentation under Annex II and III of Medical Device Regulation (EU) 2017/745