EU Conformity Assessment Procedures and STED Requirements

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Objectives of this Presentation

- Gain a basic understanding of EU technical document requirements
- Appreciate the relationship between
  - Technical Documentation
  - Conformity Assessment Routes
  - Role of National Authorities
  - Role of the Notified Bodies (3rd Parties)
- Recognise how STED fits with EU requirements of Technical Documentation

EU Technical Documentation

- TRUE or FALSE
  - *The manufacturer must prepare the technical documentation described in Annex VII*
    - Source: NIST GCR 01-815, A Guide to the EU Medical Device Directive, Delaney and van de Zande, editors, p. 22

Annex VII

- *Section 2:*
  - *The manufacturer must prepare the technical documentation described in Section 3 … must make this documentation, including the declaration of conformity, available to the national authorities …*
- *Section 3:*
  - *The technical documentation must allow assessment of the conformity of the product with the requirements of the Directive.*

Conformity Assessment Routes

Class I devices must follow the procedures specified in *Annex VII* of the Medical Device Directive.

- The involvement of a Notified Body is not needed and the manufacturer can self declare the product to be in compliance with the essential requirements of the MDD.
- With products placed on the market in sterile condition and Class I devices with a measuring function, the manufacturer must observe not only the provisions laid down in this Annex but also one of the procedures referred to in Annex IV, V or VI … in which case activities of the Notified Body is limited, but applicable.

Conformity Assessment Routes

Class IIa Devices may choose to follow any of these routes:

- Annex II,
- Annex VII *and* Annex IV,
- Annex VII *and* Annex V, or
- Annex VII *and* Annex VI.

EU Technical Documentation

- *The manufacturer is NOT always required to prepare the technical documentation as required in Annex VII.*
- *This realisation leads to many questions ….*

Questions

- Is Technical Documentation only required when using Annex IV, V, or VI together with Annex VII?
- Why does the Notified Body require the manufacturer to have “Technical Files for Annex II certification?
- What are the requirements for Class IIb and Class III devices?

EU Technical Documentation

- The term *"technical documentation"* is found 13 times in the directive.
  - Annex II, section 6.3
    - relative to Class III devices only, referring to documentation required by section 4.2 of the Annex
  - Annex III, sections 7.3, 7.4
    - referring to the documentation required section 3 of this Annex
  - Annex IV, sections 8.1, 8.2
    - relative to Class IIa devices only, referring to documentation required by Annex VII
  - Annex V, section 3.1
    - referring to the documentation required by Annex III, section 3
  - Annex V, section 6.1
    - relative to Class IIa devices only, referring to documentation required by Annex VII
  - Annex VI, section 3.1, 4.2
    - referring to the documentation required by Annex III, section 3
  - Annex VI, section 6.1
    - relative to Class IIa devices only, referring to documentation required by Annex VII

EU Technical Documentation

- Found **THREE** forms of Technical Documentation required by the MDD
  - relative to Class III devices only, referring to documentation required by section 4.2 of the Annex
  - relative to Class IIa devices only, referring to documentation required by Annex VII
  - documentation required by Annex III, section 3
- *Are there any requirements for technical documentation other than these three?*

Annex II, section 3.2 (c)

- … procedures for monitoring and verifying the design of the products …
  - *This is a form of technical documentation associated with Annex II, where section 4 is not applicable.*
    - Reference Article 11, section 3 (a). for Class IIa and IIb devices

EU Technical Documentation

- Summary – Four forms of *technical documentation*:
  - relative to Class III devices only, referring to documentation required by section 4.2 of the Annex
  - relative to Class IIa and IIb devices, referring to procedures for monitoring and verifying the design of the products required by Annex II section 3.2 (c)
  - For type examination, documentation required by Annex III, section 3
  - relative to Class IIa devices and Class I devices, referring to documentation required by Annex VII

Auditing Technical Documentation

- How far should the notified bodies go in the auditing technical documentation?
  - The MDD is very clear for the following
    - Class III
      - Annex II, section 4.3
    - Class IIb
      - Annex III, section 4.1
      - Annex II, section 3.3
    - Class IIa
      - Annex II, section 3.3

Auditing Technical Documentation

- How far should the notified bodies go in the auditing technical documentation as required by Annex VII?
  - Class IIa
    - Check procedures for controlling technical documentation and production conformity. Although there is no requirement to check all technical files for Class IIa devices, their content should be checked on a sample basis to gain confidence that the manufacturer is following the appropriate procedures and the Declarations are in the correct format. This should be checked on a sample basis for every product technology used by the manufacturer.
      - Reference: Med-dev 2.10/2 rev. 1 Annex 3

EU Technical Documentation

- The *technical documentation* is the principal means of assessment of the conformity of a product within the framework of *placing on the market* and *market surveillance* by the Member State.

EU Technical Documentation

- In Decision 90/683/EEC of 13 December 1990 the Council established that
  - “the essential objective of a conformity assessment procedure is to enable the public authorities to ensure that products placed on the market conform to the requirements as expressed in the provisions of the directives, in particular with regard to health and safety of users and consumers”.

EU Technical Documentation

- The guideline from the Council is, therefore, the essential criterion to be taken into account when considering the *content and extent of the information* to be supplied in the technical file provided for in the directives.

EU Technical Documentation

- Consequently, the *details* included in the technical file always depend
  - on the nature of the product
    - Direct link to classification, hence, to conformity assessment route
  - on necessary information to demonstrate the conformity of the product to the essential requirements of the directive.
    - Article 3, MDD

EU Technical Documentation

- To enable effective management of the technical documentation for *placing on the market* or *market surveillance*, the technical documentation is subdivided into two parts
  - PART A: Summary of the essential technical date relevant to the conformity assessment procedures
  - PART B: Technical Documentation detailing the risk analysis (management), test reports, information concerning quality manuals, plans, descriptions of products and processes, standards applied, etc.
    - Source: NB-MED/2.5.2/Rec5

EU Technical Documentation

- *Is PART A of the technical documentation equivalent to the proposed STED of GHTF?*
  - PART A contains 11 subjects
    - (i) name and address of ‘manufacturer’
    - (ii) identification of device(s) covered
    - (iii) name and addresses of facilities
    - (iv) name and address of Notified Body
    - (v) statement of the conformity assessment procedure being followed

EU Technical Documentation

- PART A contains 11 subjects
  - (vi) the declaration of conformity
  - (vii) a brief description of the device(s)
  - (viii) label and instructions for use
  - (ix) a statement of relevant regulations
  - (x) identification of technical standards with which compliance is claimed
  - (xi) a brief statement of the bench testing performed and clinical data obtained

Summary Technical Documentation

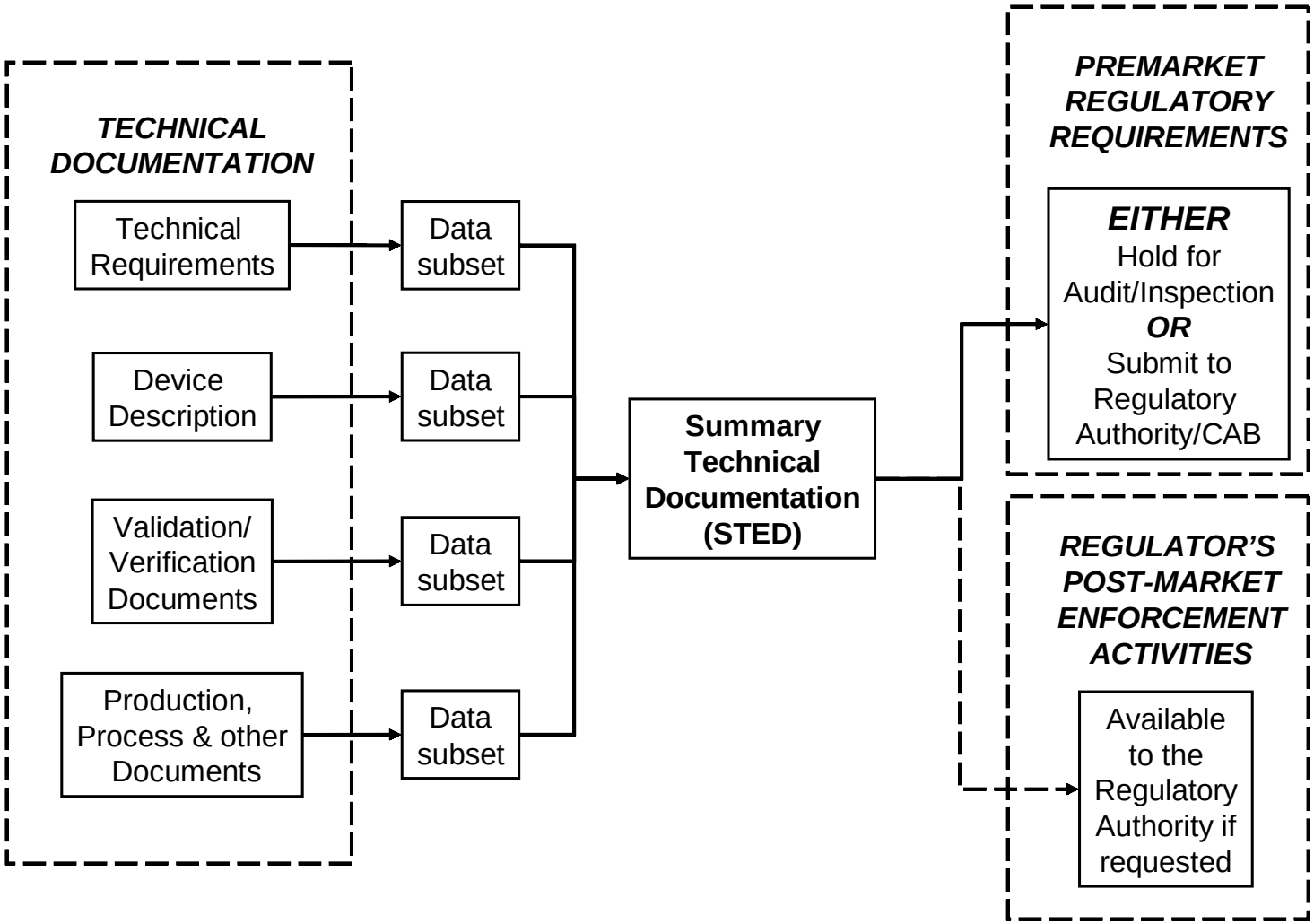

FIGURE 1: SOURCE AND APPLICATION OF THE STED

Comparisons

STED	PART A of Technical Documentation	Comments
7.1 .1 Essential Principles General	-	No details in Technical Documentation
7.1.2 Essential Principles Evidence of Conformity	(v), (vi)	Table required by STED is PART B
7.2.1 Device Description General	(ii), (vii)	

Comparisons

STED	PART A of Technical Documentation	Comments
7.2.2 Device Materials	-	PART B
7.2.3 Device Specifications	-	PART B
7.2.4 Other Device Descriptive Information	-	PART B

Comparisons

STED	PART A of Technical Documentation	Comments
7.3.1 Design V&V General	(x), (xi)	
7.3.2 Clinical Evidence	(xi) – brief statement only	Details in PART B
7.4 Labelling	(vii)	

Comparisons

STED	PART A of Technical Documentation	Comments
7.5 Risk Analysis	-	PART B
7.6 Manufacturer Information	(i), (iii)	Details of production processes and quality plans in PART B
-	(iv), (ix)	See information in STED procedure, Appendix C

Conclusion

- FOUR different requirements for Technical Documentation found in MDD
- NB-MED/2.5.1/Rec5 recommends Technical Documentation be held by manufacturer in two parts – PART A (summary) and PART B (details)
- PART A does not directly correspond with STED, in the current guidance documents available