Guidance Document:

MDR Technical Documentation Checklist

This guidance document serves as a checklist for manufacturers making an initial MDR Submission to the NSAI. It is specifically tailored to the technical documentation review.

The MDR has necessitated an increase in required documentation. Once you have submitted your Data Folder Set containing your technical documentation to NSAI a product file submission check will be performed. That assessment is directly aligned to this guidance checklist.

While this is a guidance document, its use is strongly advised for manufacturers who wish to confirm that core documents are present for the initial review.

Not all questions are required depending on the classification of your device or the relevant applicable requirements. Therefore, please use this checklist to confirm if the requirement is relevant to your submission and that the data/document has been provided.

General Requirements

1. Confirm the application form is completed and signed.	☐ Confirmed
2. Confirm that a draft DoC has been submitted to the G7 folder.	☐ Confirmed
3. Confirm that a GSPR checklist (or equivalent) has been uploaded to the G8 folder.	☐ Confirmed
4. Confirm that Labels and/or IFU have been uploaded to the L1 folder.	☐ Confirmed
5. Risk Management – Confirm that a risk management plan, risk analysis, (e.g. FMEA, HA, etc), Risk management Report, and benefit-risk analysis has been submitted in the R2 folder.	☐ Confirmed
6. Confirm that the risk management report has been signed by a clinical expert.	☐ Confirmed

Sterilisation/Sterile Barrier

7. Confirm that the S3 table has been completed on application form.	☐ Confirmed
8. Confirm that the protocol(s)/report(s) identified in S3 table, column 7 have been provided in folders S5-S8.	☐ Confirmed
9. Confirm that the routine cycle specification has been provided/table populated (S5, S6).	☐ Confirmed
10. S5 Ethylene Oxide - Confirm that residual reports have been uploaded to the S5 Folder.	☐ Confirmed
11. S6 Irradiation - Confirm that dose audits for the last year have been provided.	☐ Confirmed
12. For other sterilisation methods (If applicable), some supporting reports have been uploaded into the S8Folder.	☐ Confirmed
13. Confirm that the reports identified in S13 have been provided.	☐ Confirmed

Biocompatibility

14. Confirm that a Biological Evaluation Plan (BEP) and Report (BER), has been submitted in the BC5 folder. *Note: the BEP and BER may be combined as a single combined document.*	☐ Confirmed
15. Confirm that BEP and BER file document file name in the application form matches the BEP and BER submitted in the BC5 folder.	☐ Confirmed
16. Confirm that the BER cites all the model numbers listed in G4 of the application form.	☐ Confirmed
17. Confirm that a proof of competence/ CV for the BER author(s) has been submitted in the BC5 folder.	☐ Confirmed

Electrical

18. Confirm that a copy of 60601-1 testing has been submitted to the E2 folder.	☐ Confirmed
19. Confirm that any collateral 60601 standards listed in section E9 are submitted within the E9 folder, i.e. 60601-1-2-Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests.	☐ Confirmed
20. Confirm that any relevant particular standard testing/report listed in section E10 are included in the E10 folder i.e. 60601-2-2 for high frequency surgical equipment, 60601-2-24 for infusion pumps, 80601-2-12 for critical care ventilators etc.	☐ Confirmed

Software

21. Confirm that a list of cybersecurity documentation has been provided in the E7 folder- security risk management plan, security risk assessment (standalone or integrated).	☐ Confirmed
22. Confirm that an EN62304 E8 checklist has been completed on A form and documents fulfilling requirements are in E8 folder.	☐ Confirmed
23. Confirm that Software safety classification document has been submitted in the E8 folder.	☐ Confirmed

Mechanical Functional Safety

24. Confirm that the design functional drawings illustrate all components, their materials and dimensions i.e. not just packaging level drawings.	☐ Confirmed
25. Confirm that a device traceability and/or a design input/output matrix is provided.	☐ Confirmed
26. Confirm that design verification protocols have been supplied for each report.	☐ Confirmed
27. Confirm that device stability protocols and reports contain reference to device testing i.e. not just packaging testing.	☐ Confirmed
28. Confirm that all protocols and reports have been approved and raw data has been supplied.	☐ Confirmed

Clinical Evaluation

Section A- Personnel Involved in the Clinical Evaluation Process

29. Confirm that the CER in the C4 folder identifies the individuals/authors/evaluators who performed the clinical evaluation and does it include a description of their role.	☐ Confirmed
30. Confirm that the CVs have been provided in the C2 for each of the individuals/ authors/evaluators of the CER.	☐ Confirmed
31. Confirm that the CER includes a clinical expert/ an appropriate end user of the device under evaluation. E.g. of appropriate - heart valve- interventional cardiologist.	☐ Confirmed
32. Confirm that the CV of the clinical expert or end user of the device been provided in file.	☐ Confirmed
33. Confirm that a declaration of Interest (DOI) for each evaluator of the CER has been submitted (DOI can be found in the CER or in the CV folder).	☐ Confirmed
34. If the device is a class III or implantable device, is the clinical expert/end user appropriate and currently in practice. E.g. of appropriate - heart valve- interventional cardiologist or cardiac surgeon, contact lens ophthalmologist or optometrists (if applicable). Note: For non-implantable and class IIa devices, we can accept retired experts.	☐ Confirmed

Section B – Clinical Evaluation

35. Confirm that a Clinical Evaluation Plan (CEP) is included in C3 folder of the technical document as a separate document.	☐ Confirmed
36. Confirm that the CEP includes a Clinical Development Plan (CDP).	☐ Confirmed
37. Confirm that the CEP section of the application is referenced in the from the specific CEP requirement in the application form.	☐ Confirmed
38. Confirm that the clinical evaluation was performed by conducting either a clinical investigation or, have claimed equivalence. See statements regarding the clinical evaluation methodology in the CEP section of the application form.	☐ Confirmed
39. Confirm references to the CER in the C4 table are included, besides the given CER requirements stated in CER section of the application form.	☐ Confirmed
40. Confirm that the exact information stated in the completed Equivalence Declaration Form in CER document is included, if equivalence is claimed.	☐ Confirmed
41. Confirm that the CER in the C4 folder is dated and includes a document control number and revision number.	☐ Confirmed
42. Confirm that a statement in the CER on how often the CER will be updated is included (statement on the frequency of updates).	☐ Confirmed

43. If the expert panel was consulted by the manufacturer prior to submission, confirm that all documents showing communications with the expert panel are included.	☐ Confirmed

Section C - Equivalence

44. If Equivalence is claimed confirm it is clearly stated.	☐ Confirmed
45. Confirm the Equivalence Declaration Form is completed and submitted appropriately.	☐ Confirmed
46. For class III and implantable devices, confirm that the predicate device is a CE marked device (these classes of devices cannot claim equivalence to a non-CE mark device). **Note:** Manufacturers of lower risk devices (IIa, IIb non implantable) can claim equivalence to a non-CE marked device.	☐ Confirmed
47. For manufacturers of class III and implantable devices claiming equivalence to another manufacturer's device, confirm a contract is in place. **Note:** Manufacturers of lower risk devices do not require a contract if claiming equivalence to another manufacturer's device	☐ Confirmed
48. Confirm that the differences (if applicable) between the two devices and this is stated in the specific sections in the Equivalence Declaration Form are identified.	☐ Confirmed
49. Confirm that a scientific justification that these differences are not clinically significant in the Equivalence Declaration Form are provided, and do not affect the safety and performance of the device.	☐ Confirmed
50. Confirm that the references to the documents which support their justification for the differences between the two devices are provided E.g. tests reports, bench testing, etc.	☐ Confirmed

Section D – Clinical Investigation (C5 folder)

51. Confirm that a Clinical Investigation Plan/protocol (CIP) has been provided in the C5 folder.	☐ Confirmed
52. If there are updates to the CIP, confirm that all versions have been provided per the application form.	☐ Confirmed
53. Confirm that the Clinical Investigation Report (CIR) has been provided.	☐ Confirmed
54. If there are updates to the CIR, confirm that all versions have been provided per the application form.	☐ Confirmed
55. Confirm that approval letters from the ethics committee have been submitted (Note that any change in the Clinical investigation plan may require an Ethics Approval).	☐ Confirmed
56. Confirm that the Investigator's brochure has been submitted.	☐ Confirmed
57. Confirm that a sample of the informed consent has been submitted.	☐ Confirmed

58. Confirm that an approval letter from the Competent Authority(ies) has been submitted.	☐ Confirmed
59. Confirm that the Clinical investigation Report signed by the principal investigator(s).	☐ Confirmed

Section E – Literature Search

60. Confirm that a literature search protocol has been submitted.	☐ Confirmed
61. Confirm that a literature search Report has been submitted.	☐ Confirmed
62. Confirm that the literature search with more than one literature search databases. E.g. PubMed, Cochrane, etc.	☐ Confirmed
63. Confirm that the literature search data is up to date. This means that submitted data is within 3months in date at the time of submission.	☐ Confirmed

Section F – Post Market Section

64. Confirm that the performance and complaints analysis section been completed in the PC section of the application form.	☐ Confirmed
65. Confirm that the CER in the C4 folder includes the performance and complaints data.	☐ Confirmed
66. Confirm that the performance and complaints data is up to date. This means that submitted data is within 3months in date at the time of submission. This should be reviewed in the CER and application form.	☐ Confirmed
67. Confirm that the date range for the performance and complaints data in the application form aligns with the CER.	☐ Confirmed
68. Confirm that the performance and complaints section of the application form includes information on vigilance, CAPAs, recalls, FSCAs.	☐ Confirmed
69. Confirm that a PMS plan has been submitted.	☐ Confirmed
70. Confirm that a PMCF plan has been submitted in the C9 folder. All class III and implantable device should have a PMCF done. In rare cases where there is no PMCF plan, manufacturer should include a justification why.	☐ Confirmed
71. Confirm that PMCF report has been submitted in the C9 folder (if applicable).	☐ Confirmed
72. Confirm that PSUR has been submitted (PSURs review to begin in May 2022).	☐ Confirmed

Section G – Traceability

73. Confirm that there is traceability in the intended use statement in the CER, CEP, IFU, Risk management documents and any other core documents. The wording of the intended use statement should be exactly the same in these documents.	☐ Confirmed

Section H - General

74. Classification- Confirm that the device classification and classification rule as per MDR annex VIII are consistent with the intended use of the device.	☐ Confirmed
75. Confirm that SSCP has been submitted (if applicable). *Note that SSCPs are only indicated for implantable and class III devices.*	☐ Confirmed
76. Confirm that the IFU includes a link to find the SSCP on EUDAMED.	☐ Confirmed