Revision History

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| **Rev.** | **Date** | **Author** | **Change -Description** |
| 1.0. | 07/07/2015 | GJGD | First version |
| 2.0 | 08/12/2017 | JF | Added line at start to identify device for which Tech File has been created, plus clarification of the Parts (A and B). |

**Have the following things been provided in the Technical File (Referring to: NB-MED/2.5.1/Rec5):**

**Name of device for which this Tech File has been created:**

**Part A.**

According to NB-MED/2.5.1/Rec5, “Part A would consist of a summary of the essential technical data relevant to the conformity assessment procedures, including in particular the data listed below”.

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| Number | Subject | Further Explanation | 🗸/🗴 |
| (i) | The name and address of the ‘manufacturer’ within the meaning of the Directive(s) | Where the manufacturer is not resident in the Community, additionally the name and address of the authorised representative of the manufacturer established within the Community |  |
| (ii) | Identification of the device(s) covered by the ‘summary documentation’ | This should include the trade or proprietary name(s) if applicable, the common or usual name(s), the device classification(s) and rule(s)  assigned by the manufacturer in accordance with the relevant Directive Annex |  |
| (iii) | The name(s) and address(es) of the facilities | This should include all the facilities involved in the design and manufacture of the particular de-vice(s) covered by the ‘Summary Statement’ |  |
| (iv) | The name and address of any Notified Body involved |  |  |
| (v) | A statement of the conformity assessment procedure being followed |  |  |
| (vi) | The declaration of conformity | This would include the manufacturer’s Declaration of Conformity with the essential requirements of the medical devices Directives  Note: Where a Notified Body has been involved in the conformity assessment procedure, the Notified Body’s certificate(s) relating to the product design/type and/or the manufacturer’s quality system should be included |  |
| (vii) | A brief description of the device(s) | The description should include the intended purpose(s) and indications for use, together with a listing of any accessories |  |
| (viii) | Label and instructions for use |  |  |
| (ix) | A statement of relevant regulations | This should make clear the regulations which the products comply with, together with reference to any third party certifications and approvals |  |
| (x) | Identification of technical standards with which compliance is claimed | This should include reference to any third party certifications |  |
| (xi) | A brief statement of the bench testing performed and clinical data obtained | This should make clear how the results of bench testing and clinical data are used to demonstrate compliance with the Directive(s), and make reference to relevant part(s) of the manufacturer’s  technical documentation |  |

**Part B**

According to NB-MED/2.5.1/Rec5, “the second part (B) would consist of remaining technical documentation detailing the risk analysis, the test reports, information concerning the quality manual, plans, descriptions of the products and processes, standards applied, etc. as detailed in the previous section”.

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| Number | Subject | 🗸/🗴 |
| **3.2 Product Description** | | |
|  | a general description of the device(s) |  |
|  | a description of the intended use and operation of the device(s) |  |
|  | device(s) incorporating a medicinal substance |  |
|  | device(s) incorporating nonviable materials of animal origin |  |
|  | device(s) requiring special consideration |  |
|  | description of the methods of manufacture envisaged |  |
|  | description of the accessories, adaptors and other devices or equipment and other interfaces which are intended by the manufacturer to be used in combination with the device(s) |  |
|  | classification of the device under the relevant Directive |  |
| **3.3 Technical Requirements** | | |
|  | Identification of technical requirements |  |
|  | Solutions adopted to fulfil the essential requirements |  |
|  | Standards applied |  |
| **3.4 Design** | | |
|  | the results of the risk analysis |  |
|  | specification of materials, and manufacturing/special  processing |  |
|  | specifications, drawings and circuit diagrams for components, sub-assemblies and the complete product including packaging, where appropriate |  |
|  | the specifications of the checks, tests and trials that are intended to be carried out as part of routine production |  |
|  | the performances and compatibilities  intended by the manufacturer |  |
|  | labelling, including any instructions for use |  |
|  | identification of ‘shelf-life’ reflected by any ‘use by’ date, or other ‘lifetime’ of the device(s) |  |
|  | Results of Bench Testing |  |
|  | Clinical data |  |
|  | Documentation and reporting of Design Changes |  |
| **3.5 Administrative Details** | | |
|  | Declaration of Conformity |  |
|  | Application for Conformity Assessment |  |
|  | Declaration that no other Notified Body is used in Conformity Assessment |  |
|  | Notified Body Decisions and Reports |  |
|  | Manufacturer’s undertaking on procedure to review post-production experience |  |