

**A : Index of Technical Documentation.**

| Description.                                   | MDD ref.             | Document name.                          |
|------------------------------------------------|----------------------|-----------------------------------------|
| CD amendment controls.                         |                      | CD amendment controls.                  |
| Index & location of documents.                 |                      | Index of documentation.                 |
|                                                |                      | Location of documents.                  |
| Certificates.                                  | Annex II, V & VI.    | Declaration of conformity :             |
|                                                |                      | Notified body certification.            |
| Essential requirements & applicable standards. | Article 3.           | Essential Requirements.                 |
|                                                | Annex II para 3.2c.  | EN Standards.                           |
| Device classification & flowchart.             | Annex IX.<br>Art II. | Classification rational.                |
| EMC Rationale.                                 |                      | EMC Report.                             |
| Risk management.                               | Annex II para 3.2c.  | Risk analysis report.                   |
|                                                | Annex I para 13.     | Instructions.<br>Inserts.               |
|                                                | Annex I para 13.     | Labels.                                 |
|                                                |                      | Maintenance manual.                     |
| Product lifespan.                              |                      | Product Life.                           |
|                                                | Annex II para 3.4.   | Product Changes.                        |
| Analysis of complaints & feedback.             | Annex II para 3.1.   | Analysis of complaints / user feedback. |
| Manufacturing plan.                            | Annex II para 3.1.   | Location of responsibilities.           |
|                                                |                      | Manufacturing route.                    |
|                                                |                      | Work instructions and tests.            |
| Literature reviews.                            |                      | Literature reviews.                     |
| Packaging trials and validation.               |                      | Packaging trials and validation.        |
| Quality documentation.                         |                      | Quality Plan.                           |
| Sterilisation.                                 |                      | Sterilisation.                          |
|                                                |                      | Compliance Essential req.               |
|                                                |                      | Preliminary drawings.                   |
|                                                |                      | Preliminary drawings.                   |
|                                                |                      | Final Drawings.                         |
|                                                |                      | Working Drawings.                       |
|                                                |                      | Design review.                          |
|                                                |                      | Design changes.                         |
| Design : Output.                               | Annex II para 3.2.   | Test Reports.                           |
|                                                | Annex V & VI.        | Type examinations IEC601.               |
|                                                |                      | EMC tests.                              |
|                                                |                      | Specification Tests.                    |
|                                                | Art 15, Annex X.     | Clinical Trial Reports.                 |
|                                                |                      | Compatibility Trials.                   |
|                                                | Annex II para 3.2c.  | Biocompatibility.                       |
|                                                |                      | Validation.                             |
| Photographs.                                   |                      | Photographs.                            |
| Specifications of materials.                   |                      | Specifications of materials.            |