**LIST OF DOCUMENTS**

**to be submitted to the Notified Body (NB) PCBC for conformity assessment of the medical device**

**according to the Regulation of the Minister of Health of 17 February 2016 on essential requirements and conformity assessment procedures of medical devices (Directive 93/42/EEC) and the Regulation of the Minister of Health of 17 February 2016 on essential requirements and conformity assessment procedures of active implantable medical devices (Directive 90/385/EEC)**

|  |  |  |
| --- | --- | --- |
| **No.** | **Required documents** | |
|
| **1** | **Statements and commitments** | The copy of National Court Register document or certificate of entry in the register of business activity |
| **2** | The written declaration that no application for product assessment has been submitted to another Notified Body |
| **3** | The written declaration that no medical incidents involving the medical device applied for certification have been occurred |
| **4** | The Manufacturer’s commitment to maintain the procedures of regular review of experience gained with the device subsequent to its being placed on the market |
| **5** | The Manufacturer’s commitment to fulfil the obligations resulting from his Quality Assurance System |
| **6** | The Manufacturer’s commitment to maintain the effectiveness of the Quality Assurance System |
| **7** | The Manufacturer’s commitment to maintain the procedure in accordance with the chapter 9 of the Act on Medical Devices (the Polish Act) in case of receiving an information on medical incident |
| **8** | The written statement whether the medical device contains tissues of animal origin; fata from conducted risk analysis and risk management (Commission Regulation (EU) No. 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (if applicable) |
| **9** | The written statement whether the medical device contains the medicinal substance and the data from tests conducted due to such combination |
| **10** | The written statement whether the medical device contains the human blood derivatives and the data from tests conducted due to such combination |
| **11** | The Authorised Representative’s written statement concerning cooperation with Manufacturer (if applicable) |
| **12** | **Technical documentation of the medical device** | The description of the type of product including variants and the list of differences between variants, technical specification, intended use |
| **13** | Medical device classification, rule in accordance with Directive 93/42/EEC, the Regulation of the Minister of Health of 5 November 2010 on methods of medical device classification (Journal of Laws of the Republic of Poland No. 215, item 1416) and Manual on borderline and classification in the community, regulatory framework for medical devices version 1.17 (09-2015) |
| **14** | The essential requirements checklist (Annex 1 to the Regulation of the Minister of Health of 17 February 2016 on essential requirements and conformity assessment procedures of medical devices as amended (Journal of Laws of the Republic of Poland 2016, item 211) |
| **15** | The design drawings, the specifications of components and parts, circuit diagrams |
| **16** | The results of the design calculations |
| **17** | Validation of the manufacturing process |
| **18** | The list of harmonized standards applied in whole or in the part and other applied standards and requirements |
| **19** | Description of meeting the essential requirements, if they are not based only on the harmonized standards |
| **20** | Testing of raw materials and materials including: test results of the raw materials used to manufacture a medical device, material attestations and certificates, quality certificates and material and raw material characteristics |
| **21** | Reports from accredited laboratories on testing for conformity with harmonized standards |
| **22** | List of conducted product/raw material/material testing, with indication of accredited laboratories and scope of accreditation, any certificates of these laboratories |
| **23** | Declaration of conformity of the medical device |
| **24** | Risk management and risk analysis, including: Report of risk analysis for conformity with PN-EN ISO 14971/EN ISO 14971 |
| **25** | Biocompatibility evaluation of medical devices in accordance with PN-EN ISO 10993-1/EN ISO 10993-1 |
| **26** | Safety assessment, including technical and functional evaluation of medical devices safety, technical and functional evaluation of processed medical devices safety, biological, physical and electrical safety, restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS2) in accordance with Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of use of certain hazardous substances in electrical and electronic equipment (if applicable) |
| **27** | Evaluation of product usability in accordance with PN-EN 62366 (if applicable) |
| **28** | Verification and validation of software (if applicable) |
| **29** | Validation of measurement methods for products with a measuring function (if applicable) |
| **30** | Validation of the sterilization process including: Report of product sterilization validation which contains: installation qualification, operational qualification and process qualification, microbiological validation (if applicable) |
| **31** | Documentation of the medicinal substance according to MEDDEV 2.1/3 rev 3 (if applicable) |
| **32** | Documentation of substance being derivative from human blood, processing of tissues, cells and substances of human origin (if applicable) |
| **33** | Documentation of animal tissues in medical product according to Commission Regulation (EU) No 722/2012 of 8 August 2012 concerning particular requirements as regards the requirements laid down in Council Directives 90/385/EEC and 93/42/EEC with respect to active implantable medical devices and medical devices manufactured utilising tissues of animal origin (if applicable) |
| **34** | EDQM Certificate (if applicable) |
| **35** | Preclinical evaluation |
| **36** | The clinical evaluation (according to the Regulation of the Minister of Health of 10 March 2011 on specific conditions to be met by clinical evaluation of medical devices or active implantable devices (Journal of Laws of the Republic of Poland 2011 No. 63, item 922) |
| **37** | A draft marking (label), package (in case of translation of information documents, a formal confirmation from translation agency shall be attached) |
| **38** | Instructions for use of a medical device (in case of translation of information documents, a formal confirmation from translation agency shall be attached) |
| **39** | Brochures, folders, presentations and other promotional materials concerning medical devices prepared by the Applicant (in case of translation of information documents, a formal confirmation from translation agency shall be attached) |
| **40** | Stability tests – test report (if applicable) |
| **41** | List of all suppliers and subcontractors, indicating key critical suppliers/subcontractors; certificates of suppliers/subcontractors (if applicable) |
| **42** | **Manufacturer Quality Assurance System Documentation** | Quality Manual + Quality Policy and Objectives |
| **43** | Organizational chart and responsibilities and competencies of the management |
| **44** | Document and record control procedure |
| **45** | Risk management procedure |
| **46** | Procedure for the design of medical device |
| **47** | Procedure for the purchasing and subcontractors’ control |
| **48** | Non-complying device control procedure |
| **49** | Corrective and preventive actions procedure |
| **50** | Servicing procedure (if applicable) |
| **51** | Sterilization procedure (if applicable) |
| **52** | Product identification and traceability procedure |
| **53** | Product security procedure |
| **54** | Measuring equipment supervision procedure |
| **55** | Procedure for obtaining the feedback from users concerning product (data analysis) |
| **56** | Procedure for the testing of medical device during the manufacture process or/and testing of final product |
| **57** | Internal audit procedure |
| **58** | Product measurement procedure |
| **59** | Procedure for issuance and implementation of advisory notes |
| **60** | Procedure for dealing in case of medical incidents |
| **61** | Procedure for regular review of experience gained with the device subsequent to its being placed on the market |

**according to Regulation of the Minister of Health of 12 January 2011 on essential requirements and conformity assessment procedures of *in vitro* diagnostic medical devices (Directive 98/79/EC)**

|  |  |  |
| --- | --- | --- |
| **No.** | **Required documents** | |
|
| **1** | **Statements and Comnitments** | The copy of National Court Register document or certificate of entry in the register of business activity |
| **2** | The written declaration that no application for product assessment has been submitted to another Notified Body |
| **3** | The written declaration that no medical incidents involving the medical device applied for certification have been occurred |
| **4** | The Manufacturer’s commitment to maintain the procedures of regular review of experience gained with the *in vitro* diagnostic medical device subsequent to its being placed on the market |
| **5** | The Manufacturer’s commitment to fulfil the obligations resulting from his Quality Assurance System |
| **6** | The Manufacturer’s commitment to maintain the effectiveness of the Quality Assurance System |
| **7** | The Manufacturer’s commitment to maintain the procedure in accordance with the chapter 9 of the Act on Medical Devices (the Polish Act) in case of receiving an information on medical incident |
| **8** | The Authorised Representative’s written statement about cooperation with Manufacturer (if applicable) |
| **9** | **Technical documentation of the medical device** | The description of the type of product including variants and the list of differences between variants |
| **10** | The essential requirements checklist (Annex 1 to the Regulation of the Minister of Health of 17 February 2016 on essential requirements and conformity assessment procedures of *in vitro* diagnostic medical devices as amended (Journal of Laws of the Republic of Poland 2016, item 211) |
| **11** | The design drawings, the specifications of components and parts, circuit diagrams |
| **12** | The results of the design calculations |
| **13** | Diagram of the manufacturing process including the mid-production inspection with indication of subcontracted stages |
| **14** | The list of harmonized standards applied in whole or in the part and other applied standards |
| **15** | Description of meeting the essential requirements, if they are not based only on the harmonized standards |
| **16** | Test reports showing conformity with requirements of harmonized standards and/or Common Technical Specifications |
| **17** | Performance evaluation data confirming parameters declared by the manufacturer |
| **18** | Stability testing data confirming the stability declared by the manufacturer |
| **19** | Report of testing with participation of non-professional users (if applicable) |
| **20** | Declaration of conformity of the *in vitro* diagnostic medical device |
| **21** | Risk management and risk analysis, including: Report of risk analysis for conformity with PN-EN ISO 14971/EN ISO 14971 |
| **22** | A draft marking (label), package (in case of translation of information documents, a formal confirmation from translation agency shall be attached) |
| **23** | Instructions for use of a medical device (in case of translation of information documents, a formal confirmation from translation agency shall be attached) |
| **24** | Information on the *in vitro* diagnostic medical device restrictions |
| **25** | Information on the origin and conditions under which human tissues are derived or substances derived from these tissues - refers to medical devices containing human tissues or substances derived from these tissues |
| **26** | Brochures, folders, presentations and other promotional materials concerning *in vitro* diagnostic medical devices prepared by the Applicant (in case of translation of information documents, a formal confirmation from translation agency shall be attached) |
| **27** | List of all suppliers and subcontractors, indicating key critical suppliers/subcontractors; certificates of suppliers/subcontractors (if applicable) |
| **28** | Product sample to be consulted with the PCBC |
| **29** | **Manufacturer Quality Assurance System documentation** | Quality Manual + Quality Policy and Objectives |
| **30** | Organizational chart and responsibilities and competencies of the management |
| **31** | Document and record control procedure |
| **32** | Risk management procedure |
| **33** | Designing procedure |
| **34** | Manufacture procedure |
| **35** | Procedure for the purchasing and subcontractors’ control |
| **36** | Non-complying device control procedure |
| **37** | Corrective and preventive actions procedure |
| **38** | Servicing procedure (if applicable) |
| **39** | Sterilization procedure (if applicable) |
| **40** | *In vitro* diagnostic medical device identification and traceability procedure |
| **41** | Product security procedure |
| **42** | Measuring equipment supervision procedure |
| **43** | Procedure for obtaining the feedback from users concerning product (data analysis) |
| **44** | Procedure for the testing of *in vitro* diagnostic medical device during the manufacture process or/and testing of final product |
| **45** | Internal audit procedure |
| **46** | Product measurement procedure |
| **47** | Procedure for issuance and implementation of advisory notes |
| **48** | Procedure for dealing in case of medical incidents |
| **49** | Procedure for regular review of experience gained with the device subsequent to its being placed on the market |

**List of codes according to NBOG F 2012-1, NBOG F 2012-2, NBOG F 2012-3 (Jan 2013)**

|  |  |
| --- | --- |
| **Code** | **Name by code** |
| **MD 0000** | **Medical devices non-active, 93/42/EEC** |
| **MD 0100** | **General non-active, non-implantable medical devices** |
| **MD 0101** | Non-active devices for anaesthesia, emergency and intensive care |
| **MD 0102** | Non-active devices for injection, infusion, transfusion and dialysis |
| **MD 0103** | Non-active orthopaedic and rehabilitation devices |
| **MD 0104** | Non-active medical devices with measuring function |
| **MD 0105** | Non-active ophthalmologic devices |
| **MD 0106** | Non-active instruments |
| **MD 0107** | Contraceptive medical devices |
| **MD 0108** | Non-active medical devices for disinfecting, cleaning, rinsing |
| **MD 0110** | Non-active medical devices for ingestion |
| **MD 0200** | **Non-active implants** |
| **MD 0201** | Non-active cardiovascular implants |
| **MD 0202** | Non-active orthopaedic implants |
| **MD 0203** | Non-active functional implants |
| **MD 0204** | Non-active soft tissue implants |
| **MD 0300** | **Devices for wound care** |
| **MD 0301** | Bandages and wound dressings |
| **MD 0302** | Suture material and clamps |
| **MD 0303** | Other medical devices for wound care |
| **MD 0400** | **Non-active dental devices and accessories** |
| **MD 0401** | Non-active dental equipment and instruments |
| **MD 0402** | Dental materials |
| **MD 0403** | Dental implants |
| **MD 1000** | **Medical devices, active, 93/42/EEC** |
| **MD 1100** | **General active medical devices** |
| **MD 1101** | Devices for extra-corporal circulation, infusion and haemopheresis |
| **MD 1102** | Respiratory devices, devices including hyperbaric chambers for oxygen therapy, inhalation anaesthesia |
| **MD 1103** | Devices for stimulation or inhibition |
| **MD 1104** | Active surgical devices |
| **MD 1105** | Active ophthalmologic devices |
| **MD 1106** | Active dental devices |
| **MD 1107** | Active devices for disinfection and sterilisation |
| **MD 1108** | Active rehabilitation devices and active prostheses |
| **MD 1109** | Active devices for patient positioning and transport |
| **MD 1111** | Software |
| **MD 1112** | Medical gas supply systems and parts thereof |
| **MD 1200** | **Devices for imaging** |
| **MD 1201** | Imaging devices utilising ionizing radiation |
| **MD 1202** | Imaging devices utilising non-ionizing radiation |
| **MD 1300** | **Monitoring devices** |
| **MD 1301** | Monitoring devices of non-vital physiological parameters |
| **MD 1302** | Monitoring devices of vital physiological parameters |
| **MD 1400** | **Devices for radiation therapy and thermo terapy** |
| **MD 1401** | Devices utilising ionizing radiation |
| **MD 1402** | Devices utilising non-ionizing radiation |
| **MD 1403** | Devices for hyperthermia/hypothermia |
| **MDS 7000** | **Specifics of medical devices, 93/42/EEC and 90/ 385/EEC** |
| **MDS 7001** | Medical devices incorporating, medicinal substances, according to Directive 2001/83/EC |
| **MDS 7002** | Medical devices utilising tissues of animal origin, including Commission Regulation (EU) No 722/2012 |
| **MDS 7003** | Medical devices incorporating derivates of human blood, according to Directive 200/70/EC, amended by Directive 2001/104/EC |
| **MDS 7004** | Medical devices referencing the Directive 2006/42/EC on machinery |
| **MDS 7006** | Medical devices in sterile condition |
| **MDS 7007** | Medical devices utilising micromechanics |
| **MDS 7008** | Medical devices utilising nanomaterials |
| **MDS 7009** | Medical devices utilising biological active coatings and/ or materials or being wholly or mainly absorbed |
| **MDS 7010** | Medical devices incorporating software/ utilising software/ controlled by software |
| **AIMD 0000** | **General active implantable medical devices, 90/385/EEC** |
| **AIMD 0100** | **General active implantable medical devices** |
| **AIMD 0101** | Active implantable medical devices for stimulation/ inhibition |
| **AIMD 0103** | Active implantable medical devices substituting or replacing organ functions |

|  |  |
| --- | --- |
| **Code** | **Name by code** |
| **IVD 0000** | ***In vitro* diagnostic medical devices, 98/79/EC** |
| **IVD 0100** | **List A – Reagents and reagent products, including related calibrators and control materials, for determining the following blood group** |
| **IVD 0101** | AB0 system |
| **IVD 0102** | Rhesus (C, c, D, E, e) |
| **IVD 0103** | Anti-Kell |
| **IVD 0200** | **List A – Reagents and reagent products, including related calibrators and control materials, for the detection, confirmation and quantification in human specimens of markers** |
| **IVD 0201** | HIV infection (HIV 1 i 2) |
| **IVD 0202** | HTLV I i II |
| **IVD 0203** | Hepatitis B, C and D |
| **IVD 0300** | **List – B Reagents and reagent products and devices for self – diagnosis, including related calibrators and control materials, for determining, detection, quantification, diagnosing, evaluating** |
| **IVD 0301** | Anti-Duffy and anti-Kidd |
| **IVD 0302** | Irregular anti-erythrocytic antibodies |
| **IVD 0303** | Congenital infections: rubella, toxoplasmosis |
| **IVD 0304** | Hereditary disease: phenylketonuria |
| **IVD 0305** | Human infections: cytomegalovirus, chlamydia |
| **IVD 0306** | HLA tissue groups: DR, A, B |
| **IVD 0307** | Tumoral marker: PSA |
| **IVD 0309** | Device for self-diagnosis: device for measurement of blood sugar |
| **IVD 0400** | **Devices for self-diagnosis** |
| **IVD 0401** | Clinical chemistry |
| **IVD 0402** | Haematology |
| **IVD 0403** | Immunology |
| **IVD 0404** | Molecular biology |
| **IVD 0405** | Pregnancy and ovulation |
| **IVD 0406** | Specimen receptacles |
| **MDS 7200** | **Specifics of *in vitro* diagnostic medical devices, 98/79/EC** |
| **MDS 7205** | IVDs incorporating software / utilising software / controlled by software |
| **MDS 7206** | IVDs in sterile condition |
| **MDS 7208** | IVDs utilising nanomaterials |
| **MDS 7209** | IVDs utilising biological active coacting and/or material |
| **MDS 7210** | IVDs utilising material of human origin |