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# List of required documents for registration of medical devices in Kazakhstan:

| No. | Document name | Notes |
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| 1. | Document certifying registration in the country of manufacture or production site (Free Sale Certificate, Export Certificate, Certificate to Foreign Government) with an authentic translation into Kazakh and Russian (except for medical devices first produced in the Republic of Kazakhstan) | According to international certification standards and the certification standards established in Kazakhstan, (Apostille and notarial certification with translation), the format: PDF |
| 2. | Copy of the approval document for the right of production (Manufacturing Llicense or state license for production, FDA, extract from the Trade register), with an authentic translation into Kazakh and Russian | According to international certification standards and the certification standards established in Kazakhstan, (Apostille and notarial certification with translation), the format: PDF |
| 3. | List of documents certifying registration in other countries, indicating the number and date of issue (if any) with an authentic translation into Kazakh and Russian | Certified by the manufacturer or his authorised representative in the format: PDF |
| 4. | Copies of certificates for quality management system of medical devices manufacturer ISO 13485, GMP or relevant regional or national standard with authentic translation into Kazakh and Russian languages (provided to medical devices manufacturer and production site) | According to international certification standards and the certification standards established in Kazakhstan, (Apostille and notarial certification with translation), the format: PDF |
| 5. | Declaration of conformity with safety and performance requirements for a medical device or equivalent document with authentic translation into Kazakh and Russian | According to international certification standards and the certification standards established in Kazakhstan, (Apostille and notarial certification with translation), the format: PDF |
| 6. | Document confirming the class according to the degree of potential risk of use (Declaration of Conformity; Justification letter from the manufacturer) with authentic translation into Kazakh and Russian | Certified by the manufacturer format: PDF |
| 7. | Information regarding medical device composition (composition of the medicinal device, quantity, data on compatibility of the product with the medical device, document confirming the quality of the medicinal substance) with authentic translations in Kazakh and Russian | Certified by the manufacturer format: PDF |
| 8. | Biosafety information for a medical device containing materials of animal or human origin, based on material analysis and information on source selection (donors), material selection, processing, storage, testing, initial examination of testing procedures, and handling of tissues, cells, substances of animal or human origin, micro-organism and virus cultures with authentic translations into Kazakh and Russian | Certified by the manufacturer format: PDF |
| 9. | Report (protocol) on toxicological tests with authentic translation in Kazakh and Russian languages of results and conclusions of tests in accordance with ISO 10993 of medical devices and (or) accessories, components and consumables for medical devices, contacting with human body surface, mucous membranes, internal environment of the body (Biological Evaluation Report, Report (protocol) on toxicological tests by ISO 10993) | Certified by the manufacturer format: PDF |
| 10. | Technical test report (Test report 60601-1-2, EMC report) with authentic translation of test results and conclusions into Kazakh and Russian;<br>For medical devices (electrical): tests on electrical safety, electromagnetic compatibility. Radiation safety reports in the presence of ionising radiation | Certified by the manufacturer format: PDF |
| 11. | Stability study report justifying the shelf life of medical devices as well as sterile accessories and consumables included in the medical device package with an authentic translation into Kazakh and Russian of the test results and conclusions, including Shelf life after package opening.<br>The examination includes stability in the open vial and/or, for automated instruments, stability in the working position.<br>Stability during transportation. This information is described as follows:<br>a) the study report (including protocol, acceptance criteria);<br>b) the method of study under simulated conditions;<br>c) conclusions and recommended transportation conditions. | Certified by the manufacturer format: PDF |

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| | Stability study report on reagents and consumables included in the in vitro (IVD) diagnostic medical device package | |
| 12. | Report or test data on the specificity and analytical sensitivity of an in vitro (IVD) diagnostic medical product, including those contained in a closed type in vitro (IVD) diagnostic medical product (if applicable to the type of the designated medical device), including, if applicable no discrepancy (uncertainty), detection and quantification limits, measuring range, linearity, threshold value | Certified by the manufacturer format: PDF |
| 13. | Data on clinical (clinical-laboratory) studies (Clinical evaluation report ) with authentic Kazakh and Russian translations of the results and conclusions of the studies or available clinical data (scientific publications) | Certified by the manufacturer format: PDF |
| 14. | Information on monitoring of adverse and undesirable events (information not provided for newly designed and engineered medical devices) with authentic translation into Kazakh and Russian (Safety Report):<br>1) a list of adverse events (accidents) associated with the use of the product and an indication of the period of events;<br>2) summary overviews for each type of events and indicate the total number of events of each type reported (if there is a large number);<br>3) list of recalled medical devices and/or explanatory notifications, providing an analysis of corrective actions and measures implemented | Certified by the manufacturer or his authorised representative in the format: PDF |
| 15. | Quality document:<br>International, national or organisational standard (Technical specification, Technical File, technical conditions, specification of control methods for the finished product) with authentic translations into Kazakh and Russian of the specifications and test procedures | Certified by the manufacturer format: PDF |
| 16. | Information on medical device software (Software validation and verification report by IEC 62304):<br>results of software validation, data on its verification and primary examination, including information on its development and testing in the enterprise and in multicentre studies, data on identification and labeling of the operating system:<br>1) specify the name of the software.<br>2) specify the software version. The version tested must be accurately identified and this version corresponds to the final version of the software supplied.<br>Provide a description of the software, including identification of those functional characteristics of the product which are controlled by the software, the hardware platform, the operating system (if applicable), the use of off-the-shelf standard software (if applicable) with authentic translations into Kazakh and Russian | Certified by the manufacturer format: PDF |
| 17. | Statement of use, purpose, summary of the medical device and table of modifications and accessories (as per form) | Certified by the manufacturer or his authorised representative in the format: pdf, Excel |
| 18. | Medical device User Manual approved in the country of manufacture (original version) with authentic translation into Kazakh and Russian | The document approved in the country of manufacture shall be certified by the manufacturer. Authentic translations into Kazakh and Russian shall be certified by an authorised representative of the format: PDF |
| 19. | Instructions for use of a medical device approved in the country of manufacture with authentic translation into Kazakh and Russian | Certified by the manufacturer format: PDF |
| 20. | Draft Instructions for Medical Use of a Medical Device, in Kazakh and Russian | Certified by the applicant format: PDF, DOC |
| 21. | Medical product samples | According to the Regulations for the Expertise of a Medical Device |
| 22. | Standard samples of a medical product (if indicated in the quality document) | |
| 23. | Label | Certified by the manufacturer format: PDF |
| 24. | Description of medical device packaging (Information on packaging including, primary, secondary, batch, transport, intermediate packaging; provide information (e.g. material, composition, size).<br>Documents regulating the quality of medical product packaging materials (quality specification, certificate of analysis for primary packaging) with authentic translation into Kazakh and Russian | Certified by the manufacturer format: PDF |

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| | (Certificate of analysis, specification control report) | |
| 25. | Photo (shows the appearance of the product, accessories, consumables) | Certified by the manufacturer in format: JPEG |
| 26. | Colour layouts of packages and labels for medical devices (primary, secondary and (or), batch packaging) from manufacturer (provided in unfolded form). If there are a large number of sizes, colours, it is allowed to provide a standard layout for one of the sizes, colours (if the layouts are identical) | Certified by the manufacturer in format: PDF, JPEG |
| 27. | Draft layout of packaging, label, sticker of a medical product in Kazakh and Russian (in case of a large number of sizes, colours it is allowed to approve one layout using an abbreviation) | Certified by the manufacturer or his authorised representative in the format: PDF, DOC, JPEG |
| 28. | Justification letter for the type of in vitro diagnostic medical device (open or closed system) with authentic Kazakh and Russian translations | Certified by the manufacturer format: PDF |
| 29. | Data on the medical device sterilisation procedure, including information on the initial examination of the process, results of microbial testing (degree of bioburden), pyrogenicity, sterility (if applicable) with indication of test methods and data on the initial examination of packaging with an authentic translation into Kazakh and Russian (SOP) | Certified by the manufacturer format: PDF |
| 30. | Information on the manufacturer: name, type of activity, legal address, legal form of ownership, list of subdivisions and subsidiaries involved in the production of the medical product applied for registration, indicating their status and authority, with authentic translations into Kazakh and Russian | Certified by the manufacturer or his authorised representative in the format: PDF |
| 31. | Flow chart, Manufacturing process scheme with authentic translations into Kazakh and Russian | Certified by the manufacturer format: PDF |
| 32. | List of standards, Essential Requirements with authentic translations in Kazakh and Russian | Certified by the manufacturer in format: PDF |
| 33. | PMS - Post Market Surveillance with authentic Kazakh and Russian translations | Certified by the manufacturer in format: PDF |
| 34. | Risk analysis report with authentic Kazakh and Russian translations | Certified by the manufacturer in format: PDF |
| 35. | Marketing information (history if the medical product has been on the market for more than 2 years) (if available) | Certified by the manufacturer in format: PDF |
| 36. | Power of attorney from the manufacturer to Authorization Representative in Kazakhstan | Apostille and notarial certification with translation, the format: PDF |
| 37. | Power of attorney from the manufacturer to Pharm Consult LLP | Apostille and notarial certification with translation, the format: PDF |