自测版试剂盒CE认证需要准备什么资料

产品名称	自测版试剂盒CE认证需要准备什么资料
公司名称	全球法规注册CRO-国瑞IVDEAR
价格	.00/个
规格参数	
公司地址	光明区邦凯科技园
联系电话	13929216670 13929216670

产品详情

1. 自测版试剂盒CE认证需要准备哪些资料？

答：请参考以下资料清单：

Required documents（Take NB1434 as an example）

Statements and Comments	The copy of National Court Register document or certificate of entry in the register of business activity
	The written declaration that no application for product assessment has been submitted to another Notified Body
	The written declaration that no medical incidents involving the medical device applied for certification have been occurred
	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
	The Manufacturer ’ s commitment to fulfil the obligations resulting from his Quality Assurance System

	The Manufacturer ’ s commitment to maintain the effectiveness of the Quality Assurance System
	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
	The Authorised Representative ’ s written statement about cooperation with Manufacturer (if applicable)
Technical documentation of the medical d	The description of the type of product including variants and the list of differences between variants

evice	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)
	The design drawings, the specifications of components and parts, circuit diagrams
	The results of the design calculations
	Diagram of the manufacturing process including the mid-production inspection with indication of subcontracted stages
	The list of harmonized standards applied in whole or in the part and other applied standards
	Description of meeting the essential requirements, if they are not based only on the harmonized standards

Test reports showing conformity with requirements of harmonized standards and/or Common Technical Specifications
Performance evaluation data confirming parameters declared by the manufacturer
Stability testing data confirming the stability declared by the manufacturer
Report of testing with participation of non-professional users (if applicable)
Declaration of conformity of the in vitro diagnostic medical device
Risk management and risk analysis, including: Report of risk analysis for conformity with PN-EN ISO 14971/EN ISO 14971
A draft marking (label), package (in case of translation of information documents, a formal confirmation from translation agency shall be attached)

Instructions for use of a medical device (in case of translation of information documents, a formal confirmation from translation agency shall be attached)
Information on the in vitro diagnostic medical device restrictions
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
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)

	List of all suppliers and subcontractors, indicating key critical suppliers/subcontractors; certificates of suppliers/subcontractors (if applicable)
	Product sample to be consulted with the PCBC
Manufacturer Quality Assurance System documentation	Quality Manual + Quality Policy and Objectives
	Organizational chart and responsibilities and competencies of the management
	Document and record control procedure
	Risk management procedure
	Designing procedure
	Manufacture procedure
	Procedure for the purchasing and subcontractors' control
	Non-complying device control procedure
	Corrective and preventive actions procedure
	Servicing procedure (if applicable)
	Sterilization procedure (if applicable)

In vitro diagnostic medical device identification and traceability procedure
Product security procedure
Measuring equipment supervision procedure
Procedure for obtaining the feedback from users concerning product (data analysis)
Procedure for the testing of in vitro diagnostic medical device during the manufacture process or/and testing of final product
Internal audit procedure
Product measurement procedure
Procedure for issuance and implementation of advisory notes
Procedure for dealing in case of medical incidents
Procedure for regular review of experience gained with the device subsequent to its being placed on the market