体外诊断自测试剂盒ce认证自测公告号ce认证资料要求

产品名称	体外诊断自测试剂盒ce认证自测公告号ce认证资料要求
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

检测试剂需要符合的欧盟指令是IVDD（98/79/EEC）体外诊断器械指令

Required documents

The copy of National Court Register document or certificate of centry in the register of business activity

The witten declaration that no application for product asessment has been submitted to another Notified Body

The witten dee laration that no medical ine idents involving the medical device applied for certification have been ocurred

The Manufacturer s commitment to maintain the procedures of regular review of experience gained with the in wiro diagnostic

medical device subsequent to its being placed on the market

The Manufacturer's commitment to fulfil the obligations resuting from his Quality Assurance System

The Manufacturer S commitment to maintain the ffectiveness of the Quality Assurance Systerm

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 rceiving an infomation on medical incident

The Authorised Representative 's wrten statement about coopenation with Manufacturer (if applicable)

The description of the type of product including variants and the list of diferences between variants

The essential requirements checklist (Annex 1 to the Regulation of the Minister of Health of 17 February 2016 on essential

requirements and conformity asessment procedures of in viro diagnostic medical devices as amended (Journal of Laws of the

Republic of Poland 2016. item 211)

The design drawings. the specifications of components and purts, cirecuit 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

Stabllity 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 wiro 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 atached)

Instructions for use of a medical device (in case of translation of infomation documents, a fomal confirmation from translation

agency shall be atached)

Information on the in wiro diagnostic medical device restrictions

Information on the origin and conditions under which human tssues are derived or substunces derived from these tssues - refers

to medical devices containing human tssues or substances derived from thesc tssues

Brochures, folders, presentations and other promotional materials conceming in witro diagnostic medical devices prepared by the

Applicant (in case of tanslation of information documents. a fomal confirmation from translation ageney shall be atached)

List of all suppliers and subcontractors, indicating key critic al suppliers subcontractors; ertificates of suppliers/subcontractors (if

applicable)

Product sample to be consulted with the PCBC

- Quality Manual + Quality Policy and Obiectives

1 Organizational chart and responsibilitieis and competencies of the management

Document and recond control procedure

Risk management pxocedure

Desigming proeedure

Manufacture procedune

Proeedure for the purchasing and subcontractors' control

Noncomplying device control procedure

Correetive and preventive actions proedure

Sericing proccdure if applicable)

Sterilization procedlure (if applieable)

h vitro diagnostic medical dev ice ilentifieation and raccbility procedure

Product security procedure

Measuring equipment supervision procedure

Proedure for obraning the fedback from useTs concerming product (data analyisl

Proeedure for the 1esting of m ritro diagnostic mdical device during the manfactures process orland testing of final produnct

Intcmal audit procedure

Product measurcement proedure

Proeedure for isuance and implemenation of advisory notes

Procedure for dealing in case of medical incidents

Proeedure for regular review of experienee gained with the device subsoquent 10 its being placed on the market