# 医疗器械MDR法规CE认证

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| 产品名称 | 医疗器械MDR法规CE认证 |
| 公司名称 | 国瑞中安集团-CRO服务机构 |
| 价格 | .00/件 |
| 规格参数 | |
| 公司地址 | 深圳市光明区光源五路宝新科技园一期2#一层 |
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# 产品详情

一.欧盟医疗器械CE认证(MDR认证)

《医疗器械指令》开始于1995年1月1日生效，1998年6月13日强制实施。所有医疗器械制造商或其授权的代表应确保将要进入欧洲经济区（EEA）的医疗器械必须满足该指令要求，下面带大家了解一下。

二.医疗器械CE认证(MDR认证)适用范围

1，诊断、预防、监测、治疗或缓解疾病,

2，诊断、监测、治疗、缓解或补偿受伤或残疾,

3，调查，更换或修改解剖或生理过程的,

4，受孕控制,

三.医疗器械CE认证(MDR认证)分类：

1，Class I other 1类其他

2，Class I sterile 1类灭菌

3，Class I measurement function 1类测量

4，Class IIa 2a类

5，Class IIb 2b类

6，Class III and Class III with medicine 3类及3类带药物

1、 EU medical device CE certification (MDR certification)

The Medical Devices Directive came into force on January 1, 1995 and was enforced on June 13, 1998. All medical device manufacturers or their authorized representatives shall ensure that the medical devices that will enter the European Economic Area (EEA) must meet the requirements of the Directive. Let's take a look.

2、 Applicable scope of medical device CE certification (MDR certification)

1. Diagnose, prevent, monitor, treat or alleviate diseases,

2. Diagnose, monitor, treat, alleviate or compensate for injury or disability,

3. Investigation, replacement or modification of anatomical or physiological processes,

4. Pregnancy control,

3、 Classification of medical device CE certification (MDR certification):

1. Class I other

2. Class I sterilization

3. Class I measurement function

4. Class IIa Class 2a

5. Class IIb Class 2b

6, Class III and Class III with medicine

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