医疗器械CE认证MDR范围是有哪些

产品名称	医疗器械CE认证MDR范围是有哪些
公司名称	国瑞中安集团-实验室
价格	.00/件
规格参数	
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产品详情

MDR医疗器械法规的目的是为医疗器械制定了高标准的质量和安全标准，以满足这些产品的一般安全问题为患者和使用者提供高水平的健康保护，同时确保医疗器械在欧盟单一市场内的自由流通。MDR不仅包含了MDD及AIMDD涵盖的所有产品；还覆盖专门用于器械的清洁、消毒或灭菌的器械，以及AnnexXVI列举的无预期医疗目的的产品，如美瞳、面部填充或注射、纹身、皮肤改善和美容等产品。1.包含某些药械结合产品，详细请见Article1（8，9）。2.包含某些由非活性或处理为非活性的人类来源组织或细胞衍生物制造的特定产品。3.包含声称仅具有美容目的或另一种非医疗目的，但在功能和风险特征方面类似于医疗器械的特定产品组4.声明纳米材料器械属于MDR范围，且要接受zui为严格的评估程序。5.包含发射离子辐射的器械和医疗用途的软件。

The purpose of the MDR medical device regulation is to establish a high standard of quality and safety for medical devices, to meet the general safety problems of these products, to provide patients and users with a high level of health protection, and to ensure the free circulation of medical devices in the EU single market.

MDR not only includes all products covered by MDD and AIMDD; It also covers the devices specially used for cleaning, disinfecting or sterilizing the devices, as well as the products listed by AnnexXVI that have no intended medical purpose, such as eye beauty, facial filling or injection, tattoo, skin improvement and beauty products.

1. It contains some combination products of medicine and machinery. See Article 1 (8, 9) for details.

2. Contains certain products manufactured from tissue or cell derivatives of human origin that are inactive or treated as inactive.

3. Include specific product groups that claim to have only cosmetic purpose or another non medical purpose, but are similar to medical devices in terms of function and risk characteristics

4. Declare that nanomaterial devices belong to the scope of MDR and should be subject to the most rigorous evaluation procedures.

5. Software containing devices emitting ion radiation and medical applications.