欧盟医疗器械MDR法规上市后监管体系

产品名称	欧盟医疗器械MDR法规上市后监管体系
公司名称	国瑞中安集团-实验室
价格	.00/件
规格参数	
公司地址	深圳市光明区凤凰街道塘家社区光明高新产业园2号楼1层
联系电话	15815880040 15815880040

产品详情

加强器械上市后监管体系Chapter VIIPOST-MARKET SURVEILLANCE, VIGILANCE AND MARKET SURVEILLANCE 着重说明上市后监管、警戒和市场监管。1.建立、实施和维护上市后监管体系（见Article83）。2.强调上市后监管体系贯穿整个生命周期，并不断更新。3.建立“ 上市后监管计划 ”（见Article84），具体内容见Annex III。4.I类器械编写“ 上市后监管报告 ”（见Article85）。5.IIa、IIb和III类器械编制“ 定期安全性更新报告（PSUR） ”（见Article86）。6.PSUR需定期更新并作为技术文件的一部分。7.建立警戒和上市后监管电子系统（见Article92）。8.
在整个器械使用寿命期间，依据实施PMCF后取得的临床数据对临床评价及技术文件进行更新（Annex XIV part B）。

Strengthen the post market supervision system of devices

Chapter VIIPOST-MARKET SURVEILLANCE, VIGILANCE AND MARKET SURVEILLANCE emphasize post listing supervision, vigilance and market supervision.

1. Establish, implement and maintain the post listing regulatory system (see Article 83).

2. Emphasize that the post listing regulatory system runs through the entire life cycle and is constantly updated.

3. Establish a "post listing supervision plan" (see Article 84), and see Annex III for details.

4. Class I devices shall prepare a "post marketing regulatory report" (see Article 85).

5. Class IIa, IIb and III devices prepare "Periodic Safety Update Report (PSUR)" (see Article 86).

6. PSUR shall be updated regularly and taken as a part of technical documents.

7. Establish an electronic system for alert and post marketing supervision (see Article 92).

8. During the whole service life of the device, update the clinical evaluation and technical documents according to the clinical data obtained after the implementation of PMCF (Annex XIV part B).