如何检索医疗器械 CE 认证法规及标准

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背景信息

在日常工作中经常发现很多医疗器械厂商并不清楚如何去检索和医疗器械 CE 认证相关的法规和标准，最直接的表现就是外来文件收集这一块涉及到 CE 的法规和标准的内容比较少。如果我们把 CE 认证的工作看成是一个过程，那么该过程的重要输入无疑就是法规和标准，如果收集不全，可以想象整个申请的工作不会顺利。今天法规狗就花点时间和大家讨论一下如何把这些法规标准找全找准，**计划从四个主要途径来展开该议题，分别是：欧盟法规查询，欧盟协调标准查询，欧盟指南文件查询和公告机构联盟工作文件查询。**

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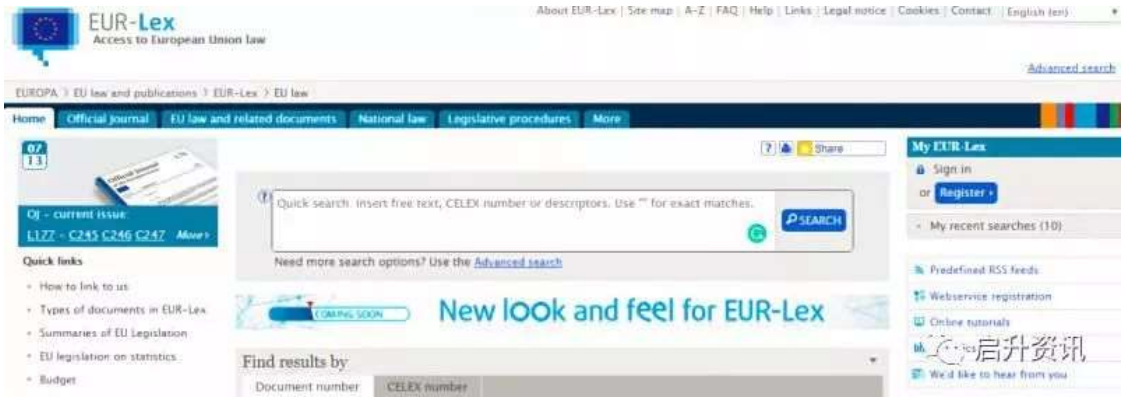
欧盟法规查询

1．网址:

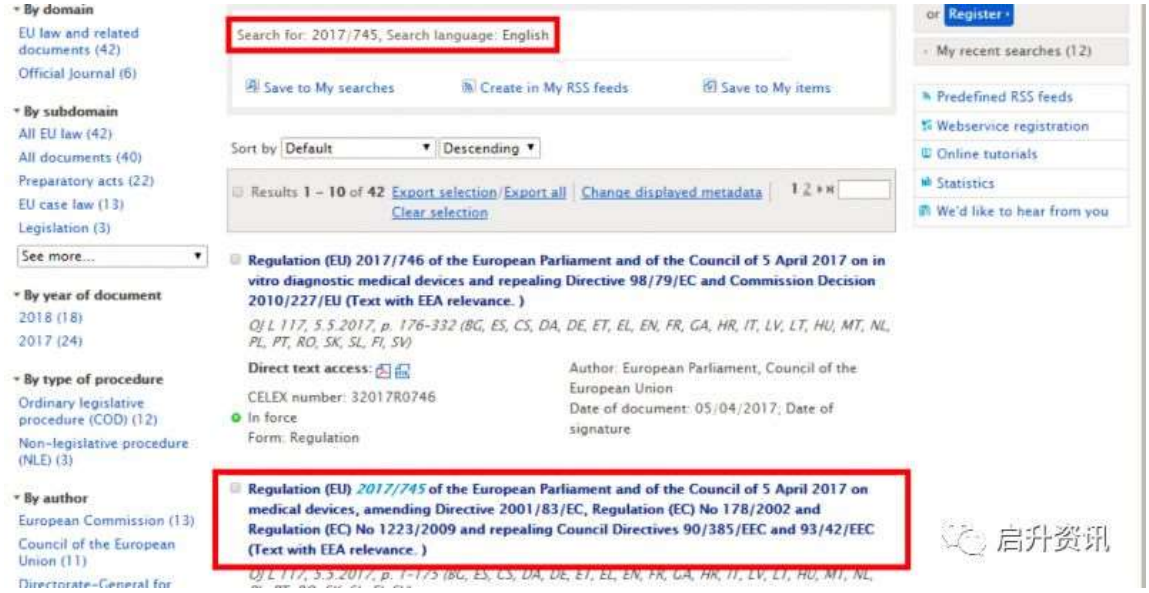
https://eur-lex.europa.eu/homepage.html；

2．简介: EUR-Lex 给公众提供免费的欧盟法规(24 种语言)的下载；

3. 界面: 请见下图;



4. 检索举例: 以查询 MDR 法规为例，在 Quick search 里面输入 2017/745，点击 Search，你就可以找到 MDR 法规了，具体请见下图。



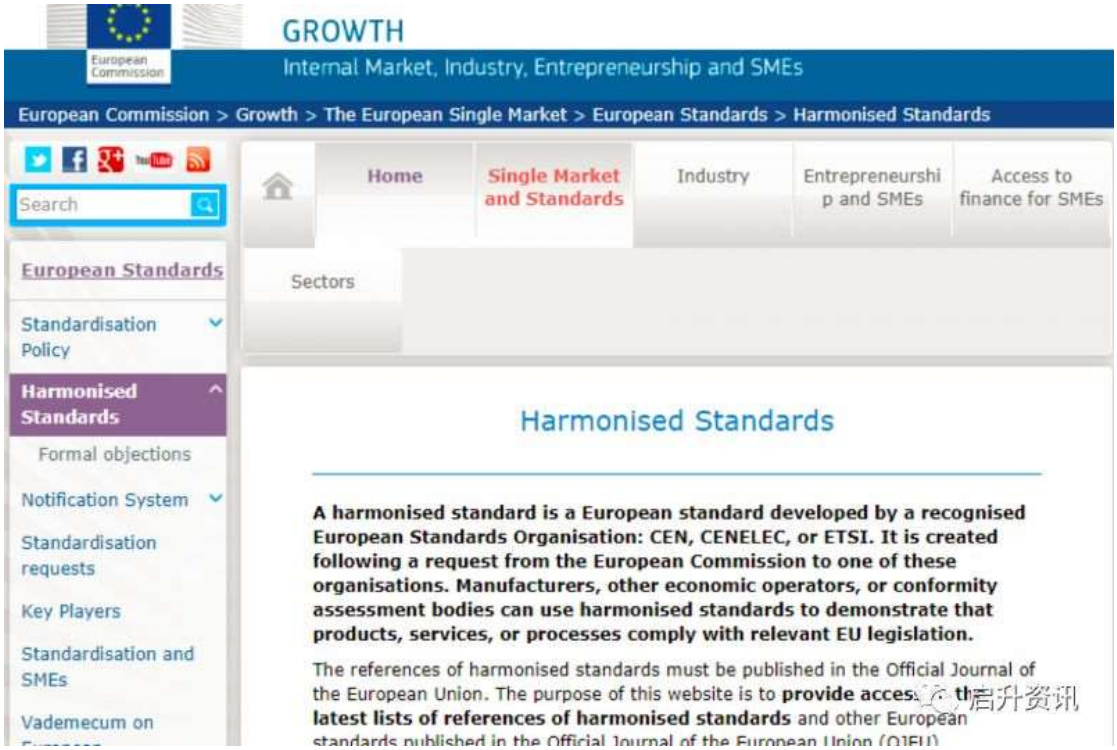
欧盟协调标准查询

1. 网址:

https://ec.europa.eu/growth/single-market/european-standards/harmonised-standards_en;

2. 简介:该网站提供了欧盟所有指令下产品的协调标准的查询途径;

3. 界面: 请见下图;



4. 检索举例: 以查询 MDD 产品的欧盟协调标准为例，下拉找到 Healthcare engineering, 然后选中 Medical device(MDD), 点击你就会看到相关的协调标准。具体请见下图。第一列是欧盟标准制定机构，第二列是标准名称和现行版本号，第三列是被欧盟接受为协调标准的时间，第四列是该标准之前的版本信息，最后一列是指新标准强制执行的时间。

ESO (1)	Reference and title of the standard (and reference document)	First publication OJ	Reference of superseded standard	Date of cessation of presumption of conformity of superseded standard Note 1
CEN	EN 285:2006+A2:2009 Sterilization - Steam sterilizers - Large sterilizers	02/12/2009	EN 285:2006+A1:2008 Note 2.1	21/03/2010

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欧盟指南文件查询

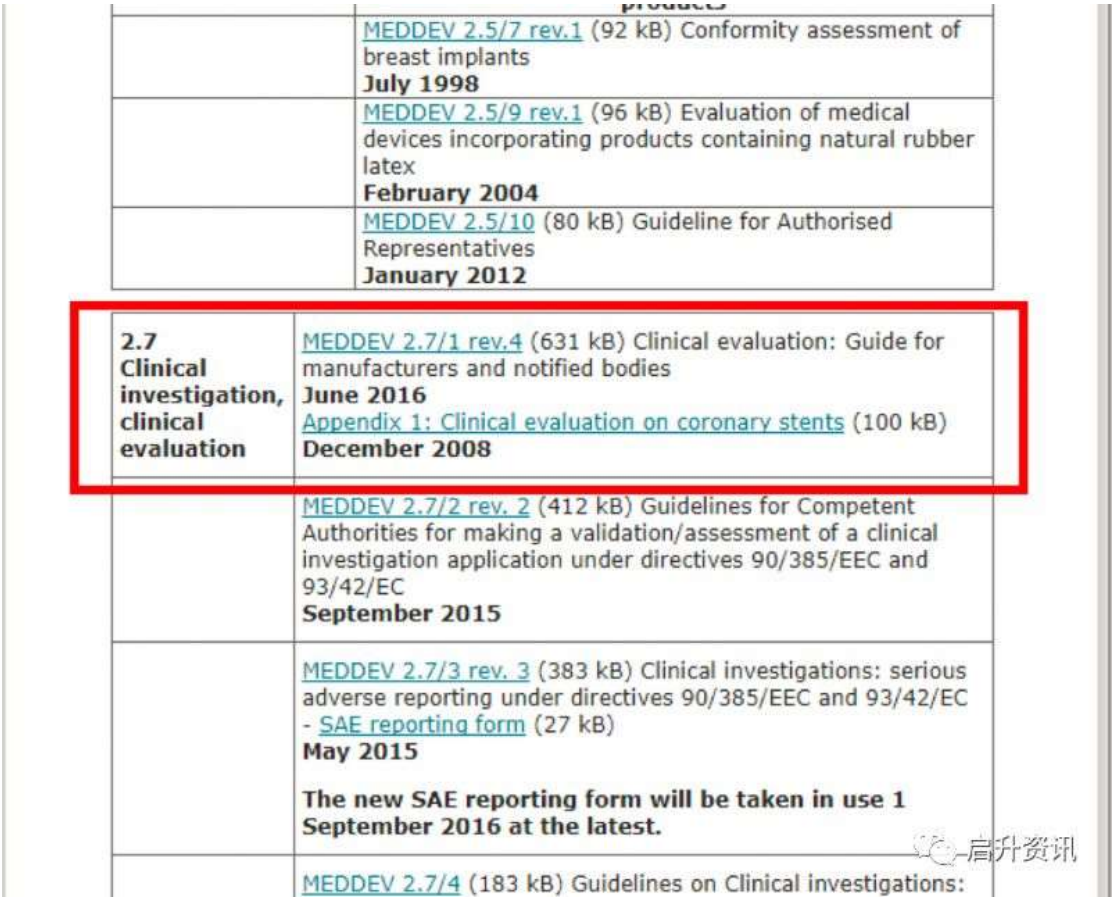
1. 网址:

https://ec.europa.eu/growth/sectors/medical-devices/guidance_en;

2. 简介: 该网址提供了 MDD, AIMD 及 IVDD 相关指南文件的查询途径;

3. 界面: 请见下图;

4. 检索举例: 以检索临床评价的要求 MEDDEV 2.7/1 Rev 4 举例，进入该网址后下拉点击 Guidance MEDDEVs，下拉你就可以看到 MEDEV 2.7/1 Rev 4 这个文件了，具体请见下图。



	MEDDEV 2.5/7 rev.1 (92 kB) Conformity assessment of breast implants **July 1998**
	MEDDEV 2.5/9 rev.1 (96 kB) Evaluation of medical devices incorporating products containing natural rubber latex **February 2004**
	MEDDEV 2.5/10 (80 kB) Guideline for Authorised Representatives **January 2012**
2.7 Clinical investigation, clinical evaluation	MEDDEV 2.7/1 rev.4 (631 kB) Clinical evaluation: Guide for manufacturers and notified bodies **June 2016** Appendix 1: Clinical evaluation on coronary stents (100 kB) **December 2008**
	MEDDEV 2.7/2 rev. 2 (412 kB) Guidelines for Competent Authorities for making a validation/assessment of a clinical investigation application under directives 90/385/EEC and 93/42/EC **September 2015**
	MEDDEV 2.7/3 rev. 3 (383 kB) Clinical investigations: serious adverse reporting under directives 90/385/EEC and 93/42/EC - SAE reporting form (27 kB) **May 2015** **The new SAE reporting form will be taken in use 1 September 2016 at the latest.**
	MEDDEV 2.7/4 (183 kB) Guidelines on Clinical investigations:

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公告机构联盟工作文件查询

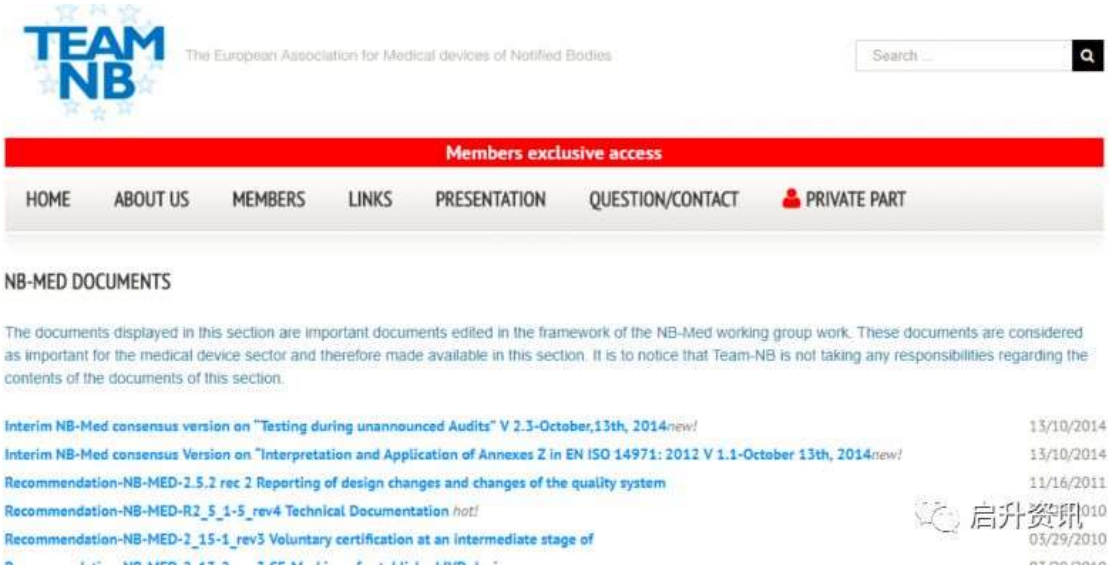
1. 网址:

http://www.team-nb.org/nb-med-documents/;

2. 简介: 为了更好地开展医疗器械的 CE 认证工作，欧盟成员国的公告机构成立联盟，定期商讨法规执行过程中碰到的问题，并形成

一些共识文件供大家作业使用，目前总共有 24 个公告机构加入该联盟，占到了所有公告机构的 40%左右。而且加入联盟的公告机构通常规模比较大，影响力也比较高，因此他们一起制定的文件还是很有参考意义的；

3. 界面: 请见下图；



4. 检索举例：以检索欧盟风险管理差异审查文件为例（**特别提醒一下广大医疗器械厂商只是满足 ISO14971:2007 Corrected version 的要求和欧盟的要求有较大差距）**进入 NB-MED document 的界面后，你会看到文件清单，其中第二个文件就是。具体请见下图。

The European Association for Medical devices of Notified Bodies

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NB-MED DOCUMENTS

The documents displayed in this section are important documents edited in the framework of the NB-Med working group work. These documents are considered as important for the medical device sector and therefore made available in this section. It is to notice that Team-NB is not taking any responsibilities regarding the contents of the documents of this section.

Interim NB-Med consensus version on "Testing during unannounced Audits" V 2.3-October,13th, 2014*new!*	13/10/2014
Interim NB-Med consensus Version on "Interpretation and Application of Annexes Z in EN ISO 14971: 2012 V 1.1-October 13th, 2014*new!*	13/10/2014
Recommendation-NB-MED-2.5.2 rec 2 Reporting of design changes and changes of the quality system	11/16/2011
Recommendation-NB-MED-R2_5_1-5_rev4 Technical Documentation *hot!*	03/29/2010
Recommendation-NB-MED-2_15-1_rev3 Voluntary certification at an intermediate stage of	03/29/2010