欧盟医疗器械检测实验室 IVDR CE认证测试实验室

产品名称	欧盟医疗器械检测实验室 IVDR CE认证测试实验室
公司名称	全球法规注册CRO-国瑞IVDEAR
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规格参数	
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产品详情

欧盟医疗器械公告机构 IVDR CE认证机构--如需办理 欢迎致电咨询！

近半数（46%）接受调查的公告机构近表示，他们不打算依照欧盟体外诊断医疗器械法规（REGULATIO N (EU)
2017/746，简称“ IVDR ”）提交指定申请，这进一步加剧了公告机构短缺与行业需求之间的矛盾。

Team-NB（European Association for Medical Devices of NBS，即欧盟医疗器械公告机构协会）进行了一项调查，旨在了解Team-NB成员公告机构根据MDR/IVDR法规框架进行指定申请的情况，以及三个现行指令（AIMDD/MDD/IVDD）下的现有范围的比较情况。在1月11日完成数据收集后一周公布了调查结果。[注：AIMDD即有源植入性医疗器械指令（Directive 90/385/EEC）；MDD即医疗器械指令（Directive 93/42/EEC）；IVDD即体外诊断医疗器械指令（Directive 98/79/EC）]

在32份调查回复中，有15个公告机构（46.8%）称他们不会依照IVDR提交指定申请，其中9个为Team-NB成员公告机构，其余6个为非Team-NB成员公告机构。Team-NB此前表示，在2018年2月对其当时的22个成员公告机构进行的调查结果显示，只有两个成员公告机构因整合计划而决定不依照IVDR提交指定申请。

新的调查结果显示，去年2月份接受调查的Team-
NB成员公告机构中只有11个依然有意向依照IVDR提交指定申请。

目前针对已经依照IVDD指定的公告机构的调查结果进一步强调了这些公告机构对依照IVDR的指定缺乏兴趣。22个已经依照IVDD指定的公告机构中，有20个正在寻求IVDR框架下的指定，包括9个非Team-NB成员公告机构和11个Team-NB成员公告机构，他们持有目前在欧洲依然有效的50～500份IVDD证书。

MedTech Europe的法规及产业政策经理Merlin Rietschel此前告诉Focus：“ 如果所有22个已经依照IVDD指定的公告机构均依照IVDR提交指定申请，每个公告机构平均需要评估至少1600个IVD产品。这意味着公告机构的工作量将会增加780%，几乎增至原来的9倍。 ”

然而，就IVDR范围而言， 8个Team-NB成员公告机构表示他们正在寻求比IVDD范围更广的指定，接下来是6个成员公告机构打算申请与IVDD范围相同的指定，还有3个成员公告机构打算申请比IVDD范围更小的指定。依照IVDR的指定也将使得两个 Team-NB成员公告机构的指定范围涵盖IVD产品。此外，大多数（81%以上）的Team-NB成员公告机构已打算或正打算申请所有用于IVDR的代码。

“这项调查的结果显示了Team-NB成员公告机构尽可能快地完成指定过程并涵盖所有代码的意图，”Team-NB表示。其中，BSI、GMED、TV SD和 UL International Ltd都在Team-NB协会的20个成员之列。

Team-NB的新调查对欧盟医疗器械法规（REGULATION (EU) 2017/745，简称“MDR”）框架下的公告机构指定流程进行了报告说明。12月11日至12月17日收集的数据显示，82%的Team-NB成员提交了MDR框架下的指定申请。相比之下，只有40%的成员提交了IVDR框架下的指定申请。考虑到MDR/IVDR的过渡期不同（分别在2020年和2022年开始施行），出现这种情况是预料之中的事。

通过进行这些调查，Team-NB对依照 IVDR指定的公告机构的预期短缺情况有了深入了解，但预计依照MDR指定的公告机构也会出现同样的短缺情况。TV SD Product Service GmbH的副总裁Bassil Akra近表示，去年甚至没有出现一个依照新法规指定的公告机构。本月初，英国BSI成为欧盟新的医疗器械法规MDR框架下正式指定的个公告机构。去年7月，MedTech Europe就MDR/IVDR过渡期内所存在的挑战提供了一些解决方案。

去年，欧盟委员会发布了一份新的工作计划和一份关于公告机构联合评估的现状报告，并讨论了与影响法规过渡的其他因素有关的问题，从而缓解了人们对分阶段实施MDR和IVDR的种种担忧。例如，英国脱欧增加了器械制造商为满足新要求做好充分准备的不确定性。英国政府计划在3月29日前实施本国版本的MDR/IVDR。

英文原文

Survey Highlights Looming Shortfall of IVDR-designated Notified Bodies

Nearly half (46%) of surveyed notified bodies (NBs) recently indicated that they do not intend to apply for designation under the European in vitro diagnostic regulation (IVDR), adding fuel to the contentious issue over the anticipated lack of NB availability to support industry demand.

Team-NB, the European association for medical devices of NBs, conducted the survey “following interest form the sector concerning the designation process in the framework of the IVDR regulation and as an act of transparency.” Results were posted about a week after data collection was completed 11 January.

Out of 32 survey responses, 15 NBs (46.8%) reported they will not apply for IVDR designation. These include nine Team-NB members and six non-members. Team-NB previously indicated that only two members would not apply to be IVDR-designated due to consolidation plans, following a February 2018 survey of its then 22 members.

The new survey results confirm the intentions to apply that 11 surveyed Team-NB members reported last February.

The lack of interest among NBs to be designated against IVDR is further underscored by the survey results around NBs currently designated against the European IVD directive, with 20 out of 22 IVDD designated NBs seeking IVDR designation. These include nine non-members and 11 Team-NB members holding between 50 and 500 IVDD certificates that are currently valid in Europe.

If all 22 of IVDD NBs applied for IVDR status, each NB “would on average need to assess at least 1,600 IVDs,” Merlin Rietschel, MedTech Europe senior manager of regulations and industrial policy, previously told Focus. “This is an increase in notified body workload of 780%, or almost by a factor of eight.”

Yet on IVDR scope, most (8) indicated they were seeking broader scopes than IVDD scopes, followed by six applications for the same scopes as IVDD and three for smaller scopes. New IVDR designations would also result in the scope of two additional Team-NB members covering IVDs for the first time. Further, most (81% or more) of Team-NB members “ intended/intend to apply for all codes ” to be used for IVDR.

“ The results of this survey confirm the intent of the Team-NB members to do their best to allow designation of notified bodies against the IVDR to be as quick as possible and covering all codes, ” Team-NB said. BSI, GMED, TV SD and UL International Ltd are among the 20 members of the association.

Team-NB ’ s last survey reports on the process for designation against the European medical device regulation (MDR). The data, which was collected between 11 December and 17 December, showed 82% of Team-NB members had submitted their applications to be designated against MDR versus just 40% in IVDR designation processes. This was to be expected considering the 2020 and 2022 transitional periods for MDR/IVDR, respectively.

The surveys offered insights into the anticipated shortfall of IVDR-designated NBs, though the same scenario is expected to occur with MDR-designated NBs too. TV SD Product Service GmbH VP Bassil Akra recently indicated that not a single NB was going to be designated last year. This prediction became reality when BSI was informed it became the first NB to be officially designated against MDR earlier this month. MedTech Europe offered certain solutions to challenges with the MDR/IVDR timelines last July.

The European Commission worked to ease concerns last year around the phased-in implementation of MDR and IVDR by releasing a new working plan and a report on the current state of joint assessments on NBs, as well as by discussing questions related to other factors influencing the transitions. Brexit, for example, adds to the uncertainty for device manufacturers to adequately prepare to meet the new requirements. The UK government intends to implement its own version of MDR/IVDR by 29 March.