Notification of a Body in the framework of a technical harmonization directive

From:

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To:

European Commission
GROWTH Directorate-General
200 Rue de la Loi,
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Other Member States

Reference: Legislation: Regulation (EU) 2017/746 on in vitro diagnostic medical devices

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Body info:

NB 2962

Tasks performed by the Body:

Last approval date: 2022-12-23

Product	Procedures	Articles /Annexes	Conditions
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-3. Devices intended to be used for markers of cancer and non-malignant tumours** **-IVR 0301 Devices intended to be used in screening, diagnosis, staging or monitoring of cancer**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-3. Devices intended to be used for markers of cancer and non-malignant tumours** **-IVR 0302 Other devices intended to be used for markers of cancer and non-malignant tumours**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-4. Devices intended to be used for human genetic testing** **-IVR 0401 Devices intended to be used in screening/confirmation of congenital/inherited disorders**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-4. Devices intended to be used for human genetic testing** **-IVR 0402 Devices intended to be used to predict genetic disease/disorder risk and prognosis**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-4. Devices intended to be used for human genetic testing** **-IVR 0403 Other devices intended to be used for human genetic testing**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	

Product	Procedures	Articles /Annexes	Conditions
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-5. Devices intended to be used to determine markers of infections/immune status** **-IVR 0501 Devices intended to be used for pre-natal screening of women in order to determine their immune status towards transmissible agents**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-5. Devices intended to be used to determine markers of infections/immune status** **-IVR 0502 Devices intended to be used to detect the presence of, or exposure to transmissible agents in blood, blood components, cells, tissues or organs, or in any of their derivatives, to assess their suitability for transfusion, transplantation or cell administration**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-5. Devices intended to be used to determine markers of infections/immune status** **-IVR 0503 Devices intended to be used to detect the presence of, or exposure to an infectious agent including sexually transmitted agents**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-5. Devices intended to be used to determine markers of infections/immune status** **-IVR 0504 Devices intended to be used to determine the infectious load, to determine infective disease status or immune status and devices used for infectious disease staging**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	

Product	Procedures	Articles /Annexes	Conditions
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-5. Devices intended to be used to determine markers of infections/immune status** **-IVR 0505 Devices intended to be used to grow/isolate/identify and handle infectious agents**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-5. Devices intended to be used to determine markers of infections/immune status** **-IVR 0506 Other devices intended to be used to determine markers of infections/immune status**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders/impairments (except human genetic testing), and therapeutic measures** **-IVR 0601 Devices intended to be used for screening/confirmation of specific disorders/impairments**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders/impairments (except human genetic testing), and therapeutic measures** **-IVR 0602 Devices intended to be used for screening, determination or monitoring of physiological markers for a specific disease**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	

Product	Procedures	Articles /Annexes	Conditions
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders/impairments (except human genetic testing), and therapeutic measures** **-IVR 0603 Devices intended to be used for screening, confirmation/determination, or monitoring of allergies and intolerances**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders/impairments (except human genetic testing), and therapeutic measures** **-IVR 0604 Other devices intended to be used for a specific disease**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders/impairments (except human genetic testing), and therapeutic measures** **-IVR 0605 Devices intended to be used for monitoring of levels of medicinal products, substances or biological components**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	

Product	Procedures	Articles /Annexes	Conditions
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders/impairments (except human genetic testing), and therapeutic measures** **-IVR 0606 Devices intended to be used for non-infectious disease staging**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders/impairments (except human genetic testing), and therapeutic measures** **-IVR 0607 Devices intended to be used for detection of pregnancy or fertility testing**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders/impairments (except human genetic testing), and therapeutic measures** **-IVR 0608 Devices intended to be used for screening, determination or monitoring of physiological markers**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	

Product	Procedures	Articles /Annexes	Conditions
-I. CODES REFLECTING THE DESIGN AND INTENDED PURPOSE OF THE DEVICE **-6. Devices intended to be used for non-infectious pathologies, physiological markers, disorders/impairments (except human genetic testing), and therapeutic measures** **-IVR 0609 Other devices intended to be used to define or monitor physiological status and therapeutic measures**	Conformity assessment based on a quality management system Conformity assessment based on assessment of technical documentation Conformity assessment based on product quality assurance	Annex IX(I) Annex IX(II) Annex XI	

Horizontal technical competences	Limitations
IVD 4001 In vitro diagnostic devices which require knowledge regarding bacteriology:	
IVD 4002 In vitro diagnostic devices which require knowledge regarding clinical chemistry/biochemistry:	
IVD 4004 In vitro diagnostic devices which require knowledge regarding genetics:	
IVD 4005 In vitro diagnostic devices which require knowledge regarding haematology/haemostasis, including coagulation disorders:	
IVD 4007 In vitro diagnostic devices which require knowledge regarding immunohistochemistry/histology:	
IVD 4008 In vitro diagnostic devices which require knowledge regarding immunology:	
IVD 4009 In vitro diagnostic devices which require knowledge regarding molecular biology/diagnostics:	
IVD 4012 In vitro diagnostic devices which require knowledge regarding virology:	
IVP 3001 In vitro diagnostic devices which require knowledge regarding agglutination tests:	
IVP 3002 In vitro diagnostic devices which require knowledge regarding biochemistry:	
IVP 3003 In vitro diagnostic devices which require knowledge regarding chromatography:	
IVP 3005 In vitro diagnostic devices which require knowledge regarding coagulometry:	
IVP 3006 In vitro diagnostic devices which require knowledge regarding flow cytometry:	
IVP 3007 In vitro diagnostic devices which require knowledge regarding immunoassays:	
IVP 3008 In vitro diagnostic devices which require knowledge regarding lysis based testing:	

Horizontal technical competences	Limitations
IVP 3010 In vitro diagnostic devices which require knowledge regarding microscopy:	
IVP 3011 In vitro diagnostic devices which require knowledge regarding molecular biological testing including nucleic acid assays and next generation sequencing (NGS):	
IVP 3012 In vitro diagnostic devices which require knowledge regarding physical chemistry including electrochemistry:	
IVP 3013 In vitro diagnostic devices which require knowledge regarding spectroscopy:	
IVS 1001 Devices intended to be used for near-patient testing:	
IVS 1002 Devices intended to be used for self-testing:	
IVS 1003 Devices intended to be used as companion diagnostics:	
IVS 1004 Devices manufactured utilising tissues or cells of human origin, or their derivatives:	
IVS 1005 Devices in sterile condition:	aseptic processing, ethylene oxide gas sterilisation (EOG), moist heat sterilisation, radiation sterilisation: gamma, radiation sterilisation: electron beam
IVS 1006 Calibrators (point 1.5 of Annex VIII to Regulation (EU) 2017/746):	
IVS 1007 Control materials with quantitative or qualitative assigned values intended for one specific analyte or multiple analytes (point 1.6 of Annex VIII to Regulation (EU) 2017/746):	
IVS 1008 Instruments, equipment, systems or apparatus:	
IVS 1009 Software that are devices in themselves including software apps, software for data analysis, and for defining or monitoring therapeutic measures:	
IVS 1010 Devices incorporating software/utilising software/controlled by software:	
IVT 2001 In vitro diagnostic devices manufactured using metal processing:	
IVT 2002 In vitro diagnostic devices manufactured using plastic processing:	
IVT 2003 In vitro diagnostic devices manufactured using non-metal mineral processing (e.g. glass, ceramics):	
IVT 2004 In vitro diagnostic devices manufactured using non-metal non-mineral processing (e.g. textiles, rubber, leather, paper):	
IVT 2005 In vitro diagnostic devices manufactured using biotechnology:	
IVT 2006 In vitro diagnostic devices manufactured using chemical processing:	

Horizontal technical competences	Limitations
IVT 2008 In vitro diagnostic devices manufactured in clean rooms and associated controlled environments:	
IVT 2009 In vitro diagnostic devices manufactured using processing of materials of human, animal or microbial origin:	
IVT 2010 In vitro diagnostic devices manufactured using electronic components including communication devices:	
IVT 2011 In vitro diagnostic devices which require packaging, including labelling:	

在技术协调指令框架内关于一个机构的通知

发件方：

联邦医疗安全办公室 - 奥地利健康与食品安全局
特赖森巷5号A-
1200 维也纳
奥地利

致：

欧盟委员会增长总司
B-1049 布鲁塞尔

其他成员国

参考： 立法依据：《体外诊断医疗器械条例》(EU) 2017/746

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NB 2962

车身信息：

车身执行任务：

最后批准日期： 2022-12-23

产品	程序	条款/附件	条件
-I. 反映设备设计和预期用途的代码 **-3. 用于标记癌症和非恶性肿瘤的设备** **-IVR 0301 用于癌症筛查、诊断、分期或监测的器械**	基于质量管理体系的符合性评估基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI	
-I. 反映器械设计和预期用途的代码 **-3. 用于癌症和非恶性肿瘤标记物的设备** **-IVR 0302 其他用于癌症和非恶性肿瘤标志物的器械**	基于质量管理体系的符合性评估基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI	
-I. 反映器械设计和预期用途的代码 **-4. 用于人类基因检测的设备** **-IVR 0401 用于筛查/确诊先天性/遗传性疾病的器械**	基于质量管理体系的符合性评估基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI	
-I. 反映器械设计和预期用途的代码 **-4. 用于人类基因检测的设备** **-IVR 0402 用于预测遗传性疾病/障碍风险及预后的器械**	基于质量管理体系的符合性评估基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI	
-I. 反映器械设计和预期用途的代码 **-4. 用于人类基因检测的设备** **-IVR 0403 其他用于人类基因检测的设备**	基于质量管理体系的符合性评估基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI	

产品	程序	条款/附件	条件
-I. 反映设备设计与预期用途的代码 **-5. 用于检测感染/免疫状态标志物的设备** **-IVR 0501 用于产前筛查女性以确定其对传染性病原体免疫状态的设备**	基于质量管理体系的符合性评估基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI	
-I. 反映器械设计和预期用途的代码 **-5. 用于检测感染/免疫状态标志物的设备** **-IVR 0502 用于检测血液、血液成分、细胞、组织或器官及其衍生物中是否存在或接触传染性病原体，以评估其输注、移植或细胞给药适用性的器械**	基于质量管理体系的符合性评估基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI	
-I. 反映器械设计和预期用途的代码 **-5. 用于检测感染/免疫状态标志物的设备** **-IVR 0503 用于检测传染性病原体（包括性传播病原体）存在或暴露情况的设备**	基于质量管理体系的符合性评估基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件 IX(I) 附件 IX(II) 附件 XI	
-I. 反映设备设计和预期用途的代码 **-5. 用于检测感染/免疫状态标志物的设备** **-IVR 0504 用于测定感染负荷、判定传染病状态或免疫状态的器械，以及用于传染病分期诊断的器械**	基于质量管理体系的符合性评估基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI	

产品	程序	条款/附件	条件
-I. 反映设备设计和预期用途的代码 **-5. 用于检测感染/免疫状态标志物的设备** **-IVR 0505 用于培养/分离/鉴定及处理传染性病原体的设备**	基于质量管理体系的符合性评估基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件九(I) 附件九(II) 附件十一	
-I. 反映器械设计和预期用途的代码 **-5. 用于检测感染/免疫状态标志物的设备** **-IVR 0506 其他用于检测感染/免疫状态标志物的设备**	基于质量管理体系的符合性评估基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI	
-I. 反映设备设计和预期用途的代码 **-6. 用于非传染性病理、生理标志物、疾病/损伤（人类基因检测除外）及治疗措施的器械** **-IVR 0601 用于特定障碍/损伤筛查/确诊的器械**	基于质量管理体系的符合性评估基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI	

-I. 反映设备设计和预期用途的代码 **-6. 用于非传染性病理、生理标志物、疾病/损伤（人类基因检测除外）及治疗措施的器械** **-IVR 0602 用于特定疾病生理标志物筛查、检测或监测的器械**	基于质量管理体系的符合性评估基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI	
产品	程序	条款/附件	条件
-I. 反映设备设计和预期用途的代码 **-6. 用于非传染性病理、生理标志物、疾病/损伤（人类基因检测除外）及治疗措施的设备** **-IVR 0603 用于过敏及不耐受筛查、确诊/判定或监测的器械**	基于质量管理体系的符合性评估基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI	
-I. 反映器械设计和预期用途的代码 **-6. 用于非传染性病理、生理标志物、疾病/损伤（人类基因检测除外）及治疗措施的器械** **-IVR 0604 其他用于特定疾病的器械**	基于质量管理体系的符合性评估基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI	

-I. 反映器械设计和预期用途的代码 **-6. 用于非传染性病理、生理标志物、疾病/功能障碍（人类基因检测除外）及治疗措施的设备** **-IVR 0605 用于监测药品、物质或生物成分水平的器械**	基于质量管理体系的符合性评估基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI	

产品	程序	条款/附件	条件
-I. 反映设备设计和预期用途的代码 **-6. 用于非传染性病理、生理标志物、疾病/损伤（人类基因检测除外）及治疗措施的设备** **-IVR 0606 用于非传染性疾病分期评估的器械**	基于质量管理体系的符合性评估基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI	
-I. 反映器械设计和预期用途的代码 **-6. 用于非传染性病理、生理标志物、疾病/损伤（人类基因检测除外）及治疗措施的器械** **-IVR 0607 用于妊娠检测或生育能力检测的器械**	基于质量管理体系的符合性评估基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件九(I) 附件九(II) 附件十一	
-I. 反映设备设计和预期用途的代码 **-6. 用于非传染性病理、生理标志物、疾病/损伤（人类基因检测除外）及治疗措施的器械** **-IVR 0608 用于生理标志物筛查、检测或监测的器械**	基于质量管理体系的符合性评估基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI	

产品	程序	条款/附件	条件
-I. 反映设备设计和预期用途的代码 **-6. 用于非传染性病理、生理标志物、疾病/损伤（人类基因检测除外）及治疗措施的设备** **-IVR 0609 其他用于定义或监测生理状态及治疗措施的器械**	基于质量管理体系的符合性评估基于技术文件评估的符合性评估 基于产品质量保证的符合性评估	附件IX(I) 附件IX(II) 附件XI	

横向技术能力	限制
IVD 4001 需要具备细菌学知识的体外诊断设备：	
IVD 4002 体外诊断设备需要临床化学/生物化学知识：	
IVD 4004 体外诊断设备，需具备遗传学知识：	
IVD 4005 体外诊断设备需具备血液学/止血学知识，包括凝血障碍：	
IVD 4007 体外诊断设备需具备免疫组织化学/组织学知识：	
IVD 4008 体外诊断设备需具备免疫学知识：	
IVD 4009 体外诊断设备需要分子生物学/诊断学知识：	
IVD 4012 需要病毒学知识的体外诊断设备：	
IVP 3001 体外诊断设备（需具备凝集试验相关知识）：	
IVP 3002 需要生物化学知识的体外诊断设备：	
IVP 3003 需要了解色谱知识的体外诊断设备：	
IVP 3005 需要凝血测定知识的体外诊断设备：	
IVP 3006 需要了解流式细胞术知识的体外诊断设备：	
IVP 3007 需要了解免疫测定知识的体外诊断设	

备：	
IVP 3008　　需要了解溶解检测技术的体外诊断设备：	
横向技术能力	限制
IVP 3010　　需要显微镜知识的体外诊断设备：	
IVP 3011　　需要分子生物学检测知识的体外诊断设备，包括核酸检测及新一代测序（NGS）：	
IVP 3012　　体外诊断设备，需具备物理化学知识（包括电化学）：	
IVP 3013　　体外诊断设备，需掌握光谱学知识：	
IVS 1001　　用于近患者检测的设备：	
IVS 1002　　用于自我检测的设备：	
IVS 1003　　作为伴随诊断使用的设备：	
IVS 1004　　利用人类来源的组织或细胞及其衍生物制造的器械衍生物：	
IVS 1005　　无菌状态下的器械：	无菌加工、 环氧乙烷气体灭菌（EOG）、湿热灭菌 、 辐射灭菌：伽马射线，辐射灭菌：电子束
IVS 1006　　校准器（欧盟法规2017/746附件VIII第1.5点）：	
IVS 1007　　具有定量或定性赋值的对照材料，适用于单一或多种分析物（欧盟法规(EU) 2017/746附件VIII第1.6点） **IVS 1008**	
IVS 1008　　仪器、设备、系统或装置：	
IVS 1009　　作为独立设备的软件，包括软件应用程序、数据分析软件，以及用于定义或监测治疗措施的软件：	
IVS 1010　　集成软件/利用软件/由软件控制的设备：	
IVT 2001　　采用金属加工制造的体外诊断设备：	

IVT 2002　　采用塑料加工制造的体外诊断设备：	
IVT 2003　　采用非金属矿物加工制造的体外诊断器械 加工技术制造的体外诊断设备（例如玻璃、陶瓷）：	
IVT 2004　　采用非金属非矿物加工制造的体外诊断设备 加工（如纺织品、橡胶、皮革、纸张）：	
IVT 2005　　采用生物技术制造的体外诊断设备：	
IVT 2006　　采用化学加工制造的体外诊断设备：	
横向技术能力	限制
IVT 2008　　在洁净室及相关受控环境中制造的体外诊断设备 受控环境中制造的体外诊断设备：	
IVT 2009　　采用人类、动物或微生物来源材料加工制造的体外诊断设备 人类、动物或微生物来源的材料加工制成的体外诊断设备：	
IVT 2010　　采用电子元件制造的体外诊断设备（包括通信设备）：	
IVT 2011　　需包装（含标签）的体外诊断设备：	