

Regulation (EU) 2017/746 IVDR D类产品通用规范

产品名称	Regulation (EU) 2017/746 IVDR D类产品通用规范
公司名称	国瑞中安集团-实验室
价格	.00/个
规格参数	
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产品详情

Common specifications This Regulation lays down common specifications for certain class D in vitro diagnostic medical devices in respect of the requirements regarding the performance characteristics set out in Section 9.1, points (a) and (b), Section 9.3 and Section 9.4, point (a), of Annex I to Regulation (EU) 2017/746.

通用规范本法规针对第2017/746号法规（EU）附件一第9.1节第（a）点和第（b）点、第9.3节和第9.4节第（a）点中规定的性能特征要求，制定了某些D类体外诊断医疗器械的通用规范。

Annex I lays down common specifications for devices covered by Annexes II to XIII, as specified in that Annex.

Annex II lays down common specifications for devices intended for detection of blood group antigens in the ABO, Rh, Kell, Duffy and Kidd blood group systems.

Annex III lays down common specifications for devices intended for detection or quantification of markers of human immunodeficiency virus (HIV) infection.

Annex IV lays down common specifications for devices intended for detection or quantification of markers of human T-cell lymphotropic virus (HTLV) infection.

Annex V lays down common specifications for devices intended for detection or quantification of markers of hepatitis C virus (HCV) infection.

Annex VI lays down common specifications for devices intended for detection or quantification of markers of hepatitis B virus (HBV) infection.

Annex VII lays down common specifications for devices intended for detection or quantification of markers of hepatitis D virus (HDV) infection.

Annex VIII lays down common specifications for devices intended for detection of markers of variant Creutzfeldt-

Jakob disease (vCJD).

Annex IX lays down common specifications for devices intended for detection or quantification of markers of cytomegalovirus (CMV) infection.

Annex X lays down common specifications for devices intended for detection or quantification of markers of Epstein-Barr virus infection (EBV).

Annex XI lays down common specifications for devices intended for detection of markers of *Treponema pallidum* infection.

Annex XII lays down common specifications for devices intended for detection or quantification of markers of *Trypanosoma cruzi* infection.

Annex XIII lays down common specifications for devices intended for detection or quantification of markers of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infection.

IVDEAR团队还可承接新冠变异株BA.4,BA.5和BA.2.75的临床实验研究、新冠前瞻性临床实验研究（含伦理批文）以及以下检测试剂：梅毒、血糖、PSA、HIV、流感、水痘、尿酸、验孕等常见产品的临床实验研究项目。