**In-Vitro Diagnostic Regulation** **(IVDR)**  
Readiness Review

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| Company Name |  | Contact Name |  |
| Address |  | Job Title |  |
|  |  | Telephone |  |
| Certification No. |  | Email |  |
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**How ready are you for the IVD Regulation?**

EU **Directives** lay down certain end results that must be achieved in every Member State. National authorities have to adapt their laws to meet these goals, but are free to decide how to do so.

**Regulations** are the most direct form of EU law - as soon as they are passed, they have binding legal force throughout every Member State, on a par with national laws. National governments do not have to take action themselves to implement EU regulations.

The IVD industry is undergoing significant change. The [IVDR](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2017:117:FULL&from=EN), which replaces the [IVD Directive (98/79/EC](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:31998L0079)), entered into force on May 25th 2017. This starts the transition period of five years for manufacturers selling IVD devices into Europe.

Manufacturers have the duration of the transition period to update their technical documentation and processes to meet the new requirements. BSI is committed to ensuring a smooth transition for all clients wishing to certify to the IVDR.

This document allows you to detail how you intend to meet the additional requirements of the new Regulation, please use in conjunction with [Regulation (EU) 2017/74](http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2017:117:FULL&from=EN)6. It is NOT an exhaustive checklist but contains summary statements of the significant changes.

Completion of this form is not mandatory and does not need to form part of the transition process, but can help with your internal preparation and be a useful tool for planning your transition strategy. Use the boxes below to list procedures, records and examples that address the additional requirements. This can be used as a gap analysis tool or as an aide memoire during your transition assessments.

Your BSI Team is here to support you on your journey, so please talk to us about your plans early on in your preparation. Further information can be found BSI IVDR revision page [www.bsigroup.com/IVDRRevision](http://www.bsigroup.com/IVDRRevision).

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| Scope  The scope of the Regulation is more specifically defined compared to the Directive, and you will need to check if you are affected by any of the following scope changes or clarifications.  **Products newly or specifically defined under Article 2:**   * ‘Prediction’ and ‘Prognosis’ of disease have been added to the definition of a medical device ([MDR Article 2](http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=OJ:L:2017:117:TOC)), which will apply to some *In vitro* diagnostic devices (IVDs) * IVD devices concerning the predisposition to a medical condition or a disease * An IVD may be a device that is software or system, either integrated or standalone, which is used *in vitro* for the examination of specimens * IVD devices with a purpose is to predict treatment response or reactions * IVD assays that are being used to provide diagnostic results either via the internet or as a ‘distant service’ (Article 6), where the result is being provided to an EU citizen.   You will need to provide information on any products that fall within the new Regulation, which were previously not covered by the Directive: |
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| **Products required to meet Common Specifications:**  **Common Specification**  Set of technical/clinical specifications other than a standard, that allows compliance with legal obligations. These may address general safety and performance requirements, clinical investigations, clinical evaluation or post-market clinical follow up.  **Implementing acts**  Include implementation measures that can be issued after the Regulation has been published. These are changes that are considered to be more procedural (eg templates, procedures, deadlines), and are used to ensure uniform application of “how” legislation is to be implemented.  **Delegated acts**  Allow amending, supplementing, or deleting non-essential elements of the legislative act. These acts have the power to change the basic requirement, or “what” of these non-essential legislative elements. The power to adopted delegated acts extends only until 25 May 2022.   * The Common Specifications (CS) under the IVDR is not yet released, however, there are CS in preparation for devices that are envisaged to be Class D under the IVDR that are currently not Annex II List A under the Directive. It is believed that the Common Technical Specifications (CTS) for the IVD Directive will convert to CS for the IVDR. * Devices that are currently Annex II List A devices under the IVD Directive will most likely be Class D under the IVDR. These devices are already expected to meet the CTS under the current IVDD. * There will be IVD devices that are not listed under Annex II of the IVD Directive, which will become Class D devices under the IVDR. * BSI believe there will be other devices for which Common Specifications will be issued. You should monitor the development of CSs for your devices that you think will be Class D under the IVDR.   **EU Reference Labs and Expert Panels**   * The IVDR brings on line a new network of EU Reference Laboratories’ (EURLs). A EURL will be involved in verifying the performance claims of Class D devices during the conformity assessment under the IVDR. * EU reference laboratories will verify by laboratory testing the performance claimed by the manufacturer and the compliance of devices presenting the highest risk with the applicable CS, when such CS are available, or with other solutions chosen by the manufacturer to ensure a level of safety and performance that is at least equivalent. * If your device will be class D but does not currently have a CS (or CTS under the IVDD), the first device placed on the market under the IVDR of its type will be required to go for an additional expert panel review.   You will need to provide information on:   * ‘If your device will be Class D but does not currently have a Common Specification (or Common Technical Specification under the IVDD), the first device placed on the market (undergoing conformity assessment) of its type will go to an expert panel’ * ‘New’ Class D devices will need to allow for potentially more transition time to the IVDR to allow for expert panel review. * Details of CTS currently used and how you will transition to the new CS under the Regulation. * Processes to check for publication of and/or changes in Common Specifications, Implementing Acts and Delegated Acts |
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Classification (Article 47 & Annex VIII)

The classification of IVDs has been radically transformed from a list-based approach in the Directive, to a rule-based approach in the Regulation. The rule-based approach comprises of four risk categories, from Class A (lowest risk) to Class D (highest risk).

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| **IVDR Classification rules:**   * Rule 1 Devices intended to be used for the following purposes are classified as class D:   + detection of the presence of, or exposure to, a transmissible agent in blood, blood components, cells, tissues or organs, or in any of their derivatives, in order to assess their suitability for transfusion, transplantation or cell administration;   + detection of the presence of, or exposure to, a transmissible agent that causes a life-threatening disease with a high or suspected high risk of propagation;   + determining the infectious load of a life-threatening disease where monitoring is critical in the process of patient management. * Rule 2 Devices intended to be used for blood grouping, or tissue typing to ensure the immunological compatibility of blood, blood components, cells, tissue or organs that are intended for transfusion or transplantation or cell administration, are classified as class C,   + except when intended to determine any of the following markers: — ABO system [A (ABO1), B (ABO2), AB (ABO3)]; — Rhesus system [RH1 (D), RHW1, RH2 (C), RH3 (E), RH4 (c), RH5 (e)]; — Kell system [Kel1 (K)]; — Kidd system [JK1 (Jka), JK2 (Jkb)]; — Duffy system [FY1 (Fya), FY2 (Fyb)]; in which case they are classified as class D. * Rule 3 Devices are classified as class C if they are intended:   + (a) for detecting the presence of, or exposure to, a sexually transmitted agent;   + (b) for detecting the presence in cerebrospinal fluid or blood of an infectious agent without a high or suspected high risk of propagation;   + (c) for detecting the presence of an infectious agent, if there is a significant risk that an erroneous result would cause death or severe disability to the individual, foetus or embryo being tested, or to the individual's offspring;   + (d) for pre-natal screening of women in order to determine their immune status towards transmissible agents;   + (e) for determining infective disease status or immune status, where there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring;   + (f) to be used as companion diagnostics;   + (g) to be used for disease staging, where there is a risk that an erroneous result would lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring;   + (h) to be used in screening, diagnosis, or staging of cancer;   + (i) for human genetic testing;   + (j) for monitoring of levels of medicinal products, substances or biological components, when there is a risk that an erroneous result will lead to a patient management decision resulting in a life-threatening situation for the patient or for the patient's offspring;   + (k) for management of patients suffering from a life-threatening disease or condition;   + (l) for screening for congenital disorders in the embryo or foetus;   + (m) for screening for congenital disorders in new-born babies where failure to detect and treat such disorders could lead to life-threatening situations or severe disabilities. * Rule 4 Self-testing and near-patient testing   + (a) Devices intended for self-testing are classified as class C, except for devices for the detection of pregnancy, for fertility testing and for determining cholesterol level, and devices for the detection of glucose, erythrocytes, leucocytes and bacteria in urine, which are classified as class B.   + (b) Devices intended for near-patient testing are classified in their own right. * Rule 5 The following devices are classified as class A:   + (a) products for general laboratory use, accessories which possess no critical characteristics, buffer solutions, washing solutions, and general culture media and histological stains, intended by the manufacturer to make them suitable for in vitro diagnostic procedures relating to a specific examination;   + (b) instruments intended by the manufacturer specifically to be used for in vitro diagnostic procedures;   + (c) specimen receptacles. * Rule 6 Devices not covered by the above-mentioned classification rules are classified as class B. * Rule 7 Devices which are controls without a quantitative or qualitative assigned value are classified as class B.     **Manufacturers are recommended to evaluate Annex VIII fully prior to completing the section below.**  You will need to provide information on the new classification of your devices: |
| Click here to type your response   |  |  |  | | --- | --- | --- | | Device | IVDD classification | IVDR Classification | | X | X | x | |  |  |  | |

Routes of Conformity (Article 48)

**Scrutiny**

The Notified Body must consult with the Commission on the adequacy of the clinical evaluation and PMCF plans prior to granting certificates for new Class D products.

**Competent Authority**

The Competent Authority is a body with authority to ensure legal enforcement of the Regulation within their Member State, to investigate vigilance issues and to remove unsafe or fraudulent devices from the Market.” The Competent Authority is also responsible for designating one or more Notified Bodies, to act as independent third party assessors of the manufacturer’s compliance.

**European Medicines Agency (EMA)**

The EMA is responsible for the scientific evaluation, supervision and safety monitoring of medicines developed by pharmaceutical companies for use in the EU.

**Products that may have changed route of conformity:**

* All IVD devices will have a new classification under the IVDR. Depending on whether you have a CE certificate under the IVD Directive, under Annex II will affect whether the re-classification changes your conformity assessment route
* If your device is listed under Annex II List A or B of the IVDD, your device is most likely to be Class D or Class C under the IVDR. For these devices, there may not be a significant change to your conformity route. However, you will need to assess the new expectations under the IVDR on evidence of conformity and role of EU Reference Laboratories.
* IVDs that were ‘self-certified’ under Annex III of the IVD Directive will most likely need to change conformity route, unless your device is Class A (non-sterile) under the IVDR.
* Class D or C devices will need to apply for either Quality Management System (QMS) Insurance Annex IX (Article 48, clause 7 for Class D, clause 7 and 8 for Class C) or Type examination Annex X and production quality assurance Annex XI (Article 48, clause 4 for Class D, clause 8 for Class C) under the IVDR.
* Class B devices will need to apply for a Quality Management System assurance Annex IX certificate (Article 48, Clause 9).
* For specific devices there will also need to be an application for assessment of technical documentation, in particular Class D devices, self-tests (class B, C or D), near patient tests (class B, C or D) and companion diagnostics.   
  For other devices, there will be an assessment of technical documentation on a sampling basis as part of the QMS or Type/QA conformity routes, per generic device group (Class C) or subcategory of devices (Class B).
* All Class D devices will require verification of performance by an EU Reference Laboratory, in addition to batch testing following certificate issue.
* Class D devices may undergo additional scrutiny (article 50) or expert panel review (article 48.6).
* Companion diagnostic devices under rule 3(f) require consultation with a national Competent Authority or EMA (article 48.8).
* Class A devices may undergo conformity assessment via self-certification, however, if the Class A device is provided sterile it will need to submit an application for Notified Body assessment with respect to the sterility aspects (Annex IX or Annex XI).
* **Please note that the Regulation does not have an equivalent to the Directive’s EC verification conformity route (98/79/EC Annex VI)**

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| **Devices shall be divided into classes A, B, C and D, taking into account the intended purpose of the devices and their inherent risks. Conformity assessment shall be carried out in accordance with Annex IX or Annex X + ANNEX XI.**  **Self-test:** means any device intended by the manufacturer to be used by lay persons, including devices used for testing services offered to lay persons by means of information society services.  **Near-patient test:** means any device that is not intended for self-testing but is intended to perform testing outside a laboratory environment, generally near to, or at the side of, the patient by a health professional;  **Companion Diagnostic:** means a device which is essential for the safe and effective use of a corresponding medicinal product to: (a) identify, before and/or during treatment, patients who are most likely to benefit from the corresponding medicinal product; or (b) identify, before and/or during treatment, patients likely to be at increased risk of serious adverse reactions as a result of treatment with the corresponding medicinal product.  **Although the Regulation indicates there are four classes of device, the routes of conformity also reference some specific types of devices that will have additional requirements as part of the conformity assessment.**  You will need to review and group your devices based on:   * Class D devices (including self-tests and near patient tests) * Self-test devices   + Class C   + Class B * Near-patient test devices   + Class C   + Class B * Companion diagnostic devices * Other Class C devices * Other Class B devices * Class A devices that are provided sterile. * Other Class A devices |
| Click here to type your response   |  |  |  | | --- | --- | --- | | Device | IVDD route to conformity | IVDR route to conformity | | X | X | x | |  |  |  | |

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| Quality Management System  **QMS Requirements to be assessed for ALL IVDR EC Certifications from 26 May 2022**  This includes:   * New requirements for performance evaluation, clinical evidence and post market performance follow-up (Article 56) * Process/Procedure for communication with Commission/Member States to obtain SRN (Article 28) * Registration of Economic Operators including Single Registration Number (Article 28) * Systems for Market Surveillance (activities described in Article 88) * Systems for Serious Incident, Field Safety Corrective Action (Article 84) and Trend Reports (Article 83) * New requirements for vigilance reporting i.e. maximum duration to report 15 days (Article 82) * Systems for PMS Plan and Report (Article 79, Article 80) * Systems for Periodic Safety Update Report (Article 81)   **Additional QMS Requirements for IVDR Applications**  You will need to provide information on:   * All systems for reclassification of devices or devices new to the scope of the IVDR (see previous sections) * Strategy for regulatory compliance (Article 10) * The new role of Person Responsible for Regulatory Compliance, PRRC, (Article 15) * Unique Device Identification and Registration (Article 24, 25) * Handling communication with regulatory authorities, Notified Bodies, economic operators (Article 10) * Economic Operators Registration (Article 28) and Single Registration Number (Article 28(2)) * EU Authorised Representative i.e. written mandate (Article 11), SRN (Article 28), PRRC (Article 15) * Importers i.e. SRN (Article 28), QMS (Article 13) * Distributors i.e. QMS (Article 14)   **Single Registration Number (SRN)**  A unique reference number given to manufacturers, authorized representatives and importers.  **Unique Device Identifier (UDI)**  Series of characters defined through internationally accepted coding to identify a specific device on the market.  **EUDAMED**  An information system for exchanging legal information related to the application of European Union Regulations.   * A process to identify General Safety & Performance Requirements (GSPR) (Article 10). See more below. * New post-market obligations for devices * New vigilance requirements.   **Changes in Activity in BSI Audits**   * All QMS audits to carry out or ask for physical/laboratory tests in order to check the QMS is working properly * Unannounced Audits frequency at least once every five years |
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General Safety & Performance Requirements (GSPR).

The GSPRs replace the IVD Directive’s Essential Requirements.

**New Requirements**

You will need to provide information on:

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| **GSPR Number** | **Comments** |
| 2, 3, 4, 5, 8 | Risk Management to EN ISO 14971:2012 |
| 9. | Performance characteristics |
| 10. | Chemical, physical and biological properties |
| 11. | Infection and microbial contamination |
| 12. | Devices incorporating materials of biological origin |
| 13. | Construction of devices and interaction with their environment |
| 14. | Devices with a measuring function |
| 15. | Protection against radiation |
| 16. | Electronic programmable systems – devices that incorporate electronic programmable systems and software that are devices in themselves |
| 17. | Devices connected to or equipped with an energy source |
| 18. | Protection against mechanical and thermal risks |
| 19. | Protection against the risks posed by devices intended for self-testing or near-patient testing |
| 20 | Label and instructions for use:   * General requirements regarding the information supplied by the manufacturer * Information on the label * Information on the packaging which maintains the sterile condition of a device (‘sterile packaging’) * Information in the instructions for use |
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Technical Documentation

**Your application to a Notified Body will require submission of Technical Documentation, either under Annex IX or Annex X.**

The submission of Technical Documentation should show the evidence of conformity to the GSPRs. it is advised that a summary is provided which covers all relevant points of Annex II and Performance evaluation and clinical evidence, refer to XIII.

For existing CE marked devices (either via a Notified Body or those devices which have been ‘self-declared) a new full application will be needed to include all technical documentation as outlined by the new regulation.

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| Clinical Evidence  **The term ‘performance evaluation’ has been redefined by the IVDR. There is a new requirement to demonstrate how a manufacturer plans to evaluate the performance of the device (‘performance evaluation’), and the output of the performance evaluation as a collation of clinical evidence in the form of a ‘Performance Evaluation Report’ (Article 56, Annex II, Annex XIII).**  You will need to provide to the notified body:  **Performance Evaluation**  ‘performance evaluation’ means an assessment and analysis of data to establish or verify the scientific validity, the analytical and, where applicable, the clinical performance of a device.  **Clinical Evidence**  ‘clinical evidence’ means clinical data and performance evaluation results, pertaining to a device of sufficient amount and quality to allow a qualified assessment of whether the device is safe and achieves the intended clinical benefit(s), when used as intended by the manufacturer.  **Performance of a device**  ‘performance of a device’ means the ability of a device to achieve its intended purpose as claimed by the manufacturer. It consists of the analytical and, where applicable, the clinical performance supporting that intended purpose.  **Scientific Validity**  ‘scientific validity of an analyte’ means the association of an analyte with a clinical condition or a physiological state.  **Analytical Performance**  ‘analytical performance’ means the ability of a device to correctly detect or measure a particular analyte.  **Clinical Performance**  ‘clinical performance’ means the ability of a device to yield results that are correlated with a particular clinical condition or a physiological or pathological process or state in accordance with the target population and intended user.   * A **Performance Evaluation Plan** (Annex XIII Part A (1.1))   You will need to provide to the notified body a **Performance Evaluation Report** (Annex XIII 1.3.2):   * A scientific validity report (Annex XIII Part A (1.2.1)) * An analytical performance report (Annex XIII Part A (1.2.2)) * A clinical performance report (Annex XIII Part A (1.2.3)) * Conclusions drawn from assessment of the clinical evidence (Article 56, 3.; Annex XIII 1.3.1) * Clinical performance studies shall be performed unless due justification is provided for relying on other sources of clinical performance data (Annex XIII 1.2.3) * Unless duly justified, self-test and near-patient test devices should have data from clinical performance studies performed in the environment in which the device is intended to be used * Additional requirements for certain types of performance studies (Article 58): * Interventional clinical performance studies (Annex XIV) * Performance studies on incapacitated subjects (Article 60) * Performance studies on minors (Article 61) * Performance studies on pregnant or breastfeeding women (Article 62) * Performance studies in emergency situations (Article 64) * Requirements for obtaining informed consent (Article 59). * For Class C and D devices a Summary of Safety and Performance will be needed (Article 29). |
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| Post-Market Surveillance (PMS) Requirements  **Post-market surveillance (Article 88), market surveillance, vigilance, registration of economic operators shall be applicable to ALL devices placed on the market or put into service from the date of application, 26th May 2022.**  This includes:   * PMS Plan (Article 79). A PMS Plan shall be provided at the time of initial application. * PMS Report (Article 80) * Periodic Safety Update Report (Article 81) * Serious Incident, Field Safety Corrective Action (Article 82) * Trend Report (Article 83) * Market Surveillance (activities described in Article 88) * Registration of Economic Operators including Single Registration Number (Article 27, 28)   You will need to provide information on:   * How to meet the new IVDR requirement i.e. maximum duration to reporting 15 days * Meet the new IVDR requirement on post market performance follow-up * Process/Procedure for communication with Commission/Member States to obtain SRN * Process/Procedure to provide PSUR at frequency described by Article 81 * EU Authorized Representative i.e. written mandate (Article 11), SRN (Article 28), PRRC (Article 15), * Importers i.e. SRN (Article 28), QMS (Article 13) * Distributors i.e. QMS (Article 14) |
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Other Changes

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| **New requirements**  You will need to provide information on:   * Declaration of Conformity (Article 17 & Annex IV) * Unique Device Identification –Based on the classification of the device (transition provision 113) UDI obligations will come into act from: * Class D: 26 May 2023 * Class C and B: 26 May 2025 * Class A: 26 May 2027. * EUDAMED – obligations start from the date of application (Article 30). There are transition arrangements for the implementation of EUDAMED under Article 110. |
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Description: BSI Core Logo Black and Red Dot CMYKWhen responses are complete please share with your Scheme Manager as “readiness review”; this will help plan the transition described by Article 110.

Visit us online at: [bsigroup.com/medical](http://bsigroup.com/medical)

**BSI Group America Inc.**

12950 Worldgate Drive,   
Suite 800,

Herndon,   
VA 20170  
USA

T: +1 800 862 4977/703 437 9000

F: +1 703 437 9001

E: us.medicaldevices@bsigroup.com

**BSI Group - EMEA**  
Kitemark Court,  
Davy Avenue,  
Knowlhill,  
Milton Keynes MK5 8PP  
United Kingdom

T: +44 345 080 9000  
F: +44 1908 814920  
E: eu.medicaldevices@bsigroup.com

**BSI Group Asia Pac**

BSI Group - Hong Kong  
23rd Floor, Cambridge House  
TaiKoo Place,   
979 King’s Road,  
Island East, Hong Kong

T: +852 3149 3320

F: +852 2743 8727

E: hk@bsigroup.com

**BSI Group The Netherlands B.V**

Say Building  
John M. Keynesplein 9  
1066 EP Amsterdam   
The Netherlands

T: +31 346 0780

F: +31 346 0781

E: eu.medicaldevices@bsigroup.com

Find out more about how BSI   
can support your transition   
by visiting our website [**bsigroup.com/IVDRRevision**](http://www.bsigroup.com/IVDRRevision)

or call: **+44 345 080 9000**

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