**Annex ZZ**

(informative)

**Relationship between this European standard and** **the General Safety and Performance Requirements of Regulation (EU) 2017/746 aimed to be covered**

This European standard has been prepared under the European Commission’s standardisation request *[Full reference to the request “M/xxx”]*[[1]](#footnote-1)to provide one voluntary means of conforming to the General Safety and Performance Requirements of Regulation (EU) 2017/746 of 5 April 2017 concerning *in vitro* diagnostic medical devices [OJ L 117].

Once this standard is cited in the Official Journal of the European Union under that Regulation, compliance with the normative clauses of this standard given in Table ZZ.1 confers, within the limits of the scope of this standard, a presumption of conformity with the corresponding General Safety and Performance Requirements of that Regulation, and associated EFTA regulations.

NOTE 1 The standard’s scope is limited to the specific uses, environments, contexts, objective situations specifically indicated. It cannot provide for presumption of conformity in other conditions. Some clauses or subclauses may be not applicable due to the specific type of equipment under consideration.

NOTE 2 Only prescriptions contained in the normative parts of the text are relevant to the presumption of conformity of this standard. Informative parts may, however, support users to interpret such prescriptions correctly.

NOTE 3 Where a reference from a clause of this standard to the risk management process is made, the risk management process needs to be in compliance with Regulation (EU) 2017/746. This means that risks have to be ‘reduced as far as possible’, ‘reduced to a level as low as reasonably practicable’, ‘reduced to the lowest possible level’, ‘reduced as far as possible and appropriate’, ‘removed or reduced as far as possible’, ‘eliminated or reduced as far as possible’, ‘prevented’ or ‘minimized’, according to the wording of the corresponding General Safety and Performance Requirement.

NOTE 4 The manufacturer’s policy for determining **acceptable risk** must be in compliance with General Safety and Performance Requirements 1, 2, 3, 4, 5, 8, 10, 11, 13, 15, 16, 17, 18 and 19 of the Regulation.

NOTE 5 For all parts of this standard that a) refer in their clauses to specific national legislation possibly exempting manufacturers from the thorough application of relevant provisions of this standard or b) link the completion of a relevant process/prescription to any discretional choice/power of manufacturers, the user of the standard should check that such clauses are in compliance with Regulation (EU) 2017/746.

*[Only for an EN IEC under IEC or CENELEC lead* NOTE 6 This Annex ZZ is based on normative references according to the table of references in the European Foreword, replacing the references in the core text.

NOTE 7 When a General Safety and Performance Requirement does not appear in Table ZZ.1, it means that it is not addressed by this European Standard.

**Table ZZ.1 – Correspondence between this European standard and Annex I of Regulation (EU) 2017/746 [OJ L 117]**

|  |  |  |
| --- | --- | --- |
| General Safety and Performance Requirements of Regulation (EU) 2017/746 | Clause(s) / sub-clause(s)  of this EN | Remarks / Notes |
| *[Only one GSPR per row]*  *[Rows ordered according to the numerical order of the GSPRs]* |  | *[To be filled in with any explanations needed to clarify the coverage of the GSPR.]* |
|  |  |  |

[NOTE to the drafter, to be removed before publication:

This table is to be used to declare a detailed correspondence between the GSPR and the clauses/sub-clauses of the standard. Please use as many rows as needed).]

WARNING 1: Presumption of conformity stays valid only as long as a reference to this European standard is maintained in the list published in the Official Journal of the European Union. Users of this standard should consult frequently the latest list published in the Official Journal of the European Union.

WARNING 2: Other Union legislation may be applicable to the product(s) falling within the scope of this standard.

*If required* For devices which are also machinery within the meaning of Article 2(a) of Directive 2006/42/EC on Machinery, in accordance with Article 1(6) of Regulation (EU) 2017/746, the following Table ZZ.2 details the relevant Essential Health and Safety Requirements of Directive 2006/42/EC on Machinery to the extent to which they are more specific than the General Safety and Performance Requirements set out in Chapter II of Annex I of Regulation (EU) 2017/746 along with the corresponding clauses of this European Standard. Table ZZ.2, however, does not imply any citation in the OJEU under the machinery directive and thus does not provide presumption of conformity for the machinery directive.

**Table ZZ.2 — Relevant Essential Health and Safety Requirements from Directive 2006/42/EC on machinery that are addressed by this Document (according to article 1, item 6, of Regulation (EU) 2017/746)**

|  |  |  |
| --- | --- | --- |
| Essential Health and Safety Requirements of Directive 2006/42/EC | Clause(s) / sub-clause(s)  of this EN | Remarks / Notes |
| *[Only one EHSR per row]*  *[Rows ordered according to the numerical order of the EHSRs]* |  | *[To be filled in with any explanations needed to clarify the coverage of the EHSR.]* |
|  |  |  |

1. Replace with the reference number and title of the relevant standardisation request. [↑](#footnote-ref-1)