

PRODUCT

COMPLIANCE UPDATE

2019 Issue 1

This issue:

Headlines

Standards Watch

European standards being withdrawn

Other standards being withdrawn

Lists of European Harmonised Standards

Brexit

Draft UK Legislation

No Deal Brexit - UK Conformity Assessed Mark

New Standards – a quick overview

CEN/TR 10364:2018

PD IEC GUIDE 116:2018

New Standards Published

December 2018

January 2019

February 2019

Compliance Calendar



Headlines

New Harmonised Standards lists published in the OJEU for:

There have been no new lists of Harmonised Standards published in the OJEU since the 2018 Issue 6 newsletter.

The Brexit Clock



Fri 29 March 2019

4 weeks to go (maybe)

Standards being withdrawn (see standards watch)

- **within 1 year**
 - European Standards none identified
 - Other Standards none identified
- **within 2 years**
 - European Standards 4 standards
 - Other Standards none identified

Note: Where references are made to expiry dates these are the dates published in the standards, and not necessarily the dates published in the OJEU

If you want to know more, contact us

Standards Watch

Changes to standards and EU Directives that impact on product compliance



European standards being withdrawn

The following standards are being withdrawn, at which time they will no longer provide a presumption of conformity for CE marking:

Within 12 months

Date	Old standard	Subject	New standard

Within 2 years

Date	Old standard	Subject	New standard
21 Apr 2020	EN 55011:2016	EMC	EN 55011:2016 + A1:2017
22 Jun 2020	EN 61000-4-11:2004		EN 61000-4-11:04 + A1:17
17 Aug 202	EN 62321-4:2014	RoHS	EN 62321-4:14 + A1:17
08 Sep 2020	EN 61000-4-5:2014	EMC	EN 61000-4-5:04 + A1:17

European harmonised standards are regularly updated

Care should be taken to make sure product compliance is kept up to date

Other standards being withdrawn

Within 12 months

Date	Old standard	Country	New standard

Within 2 years

Date	Old standard	Country	New standard

Lists of European Harmonised Standards

Published in the Official Journal of the EU and giving presumption of conformity with the essential requirements of the relevant Directive.

Directive	OJEU Ref	Date
EMC	2018/C 246/01	13 Jul 2018
LVD	2018/C 326/02	14 Sep 2018
Radio Equipment Directive	2018/C 326/04	14 Sep 2018
Machinery Directive	2018/C 092/01	09 Mar 2018
RoHS Directive	2012/C 363/05	23 Nov 2012
Medical Devices Directive	2017/C 389/03	17 Nov 2017
Active Implantable Medical Devices	2017/C 389/02	17 Nov 2017
In Vitro Diagnostic Medical Devices	2017/C 389/04	17 Nov 2017

Further information:



Brexit



Draft UK Legislation

A series of “draft” regulations have been laid before parliament. Some of these regulations correspond to multiple EU Directives:

Directive	UK Statutory Instruments	Schedule
RED	Product Safety and Metrology etc. (Amendment etc.) (EU Exit) Regulations 2019	28
LVD		23
EMC		20
RoHS	The Waste (Miscellaneous Amendments) (EU Exit) (No. 2) Regulations 2019	18
WEEE		8 & 9
Batteries		5 & 13
Packaging		20
REACH	The REACH etc. (Amendment etc.) (EU Exit) Regulations 2019	All
	The Electronic Communications and Wireless Telegraphy (Amendment etc.) (EU Exit) Regulations 2019	



No Deal Brexit - UK Conformity Assessed Mark

Applicable ONLY in the case of a no deal Brexit

The UKCA (UK Conformity Assessed) mark would replace the CE mark if we leave the EU without a deal.

There are UK guidance documents supporting this:

- [Using the UKCA marking if the UK leaves the EU without a deal](#)
- [Standard form of the UKCA marking](#)

The following general rules apply (very similar to the rules that apply to the CE mark):

- UKCA markings must only be placed on a product by you as the manufacturer or your authorised representative (where allowed for in the relevant legislation)
- when attaching the UKCA marking, you take full responsibility for your product’s conformity with the requirements of the relevant legislation
- you must only use the UKCA marking to show product conformity with the relevant UK legislation
- you must not place any marking or sign that may misconstrue the meaning or form of the UKCA marking to third parties
- you must not attach other markings on the product which affect the visibility, legibility or meaning of the UKCA marking
- the UKCA marking cannot be placed on products unless there is a specific requirement to do so in the legislation
- The UKCA marking will not be recognised by the EU, and products currently requiring a CE marking will continue to require one for sale in the EU.

New Standards – a quick overview



CEN/TR 10364:2018

“Steels and cast irons - Determination of substances listed in the directives 2011/65/EU (RoHS) and 2000/53/EC (ELV) – Limitations”

General

- Guidance on controls of steels (except chrome plated products) and cast irons for RoHS & ELV

Conclusion

- Collection of evidence can be focussed on:
 - lead in the bulk materials;
 - hexavalent chromium - on the surface of some products

Caveats

- *The surface may get contaminated or may undergo surface reactions.*
- *Further processing/treatments, may result in un-wanted substances on the surface*



PD IEC GUIDE 116:2018

“Guidelines for safety related risk assessment and risk reduction for low voltage equipment”

Explains how “Failure Modes and Effects Analysis (FMEA)”, including “Failure Modes, Effects and Criticality Analysis (FMECA)”, is planned, performed, documented and maintained .

This 3rd edition replaces the 2nd edition 2006 – main changes are:

- the normative text is generic and covers all applications;
- examples for safety, automotive, software and (service) processes added;
- tailoring the FMEA for different applications is described;
- different reporting formats are described, including a database information system;
- alternative means of calculating risk priority numbers (RPN) have been added;
- a criticality matrix based method has been added;
- the relationship to other dependability analysis methods have been described

See also **BS EN ISO 12100:2010** “Safety of machinery — General principles for design — Risk assessment and risk reduction”

New Standards Published

National and international standards of interest published in recent months

December 2018

BS EN IEC 60812:2018	Failure modes and effects analysis (FMEA and FMECA)
BS ISO 30401:2018	Knowledge management systems. Requirements
EN 55016-4-2:2011/A2:2018	Specification for radio disturbance and immunity measuring apparatus and methods. Uncertainties, statistics and limit modelling. Measurement instrumentation uncertainty
IEC GUIDE 116:2018	Guidelines for safety related risk assessment and risk reduction for low voltage equipment
ISO 30401:2018	Knowledge management systems. Requirements

January 2019

BS EN IEC 62881:2018	Cause and effect matrix
PD CEN/TR 10364:2018	Steels and cast irons. Determination of substances listed in the directives 2011/65/EU (RoHS) and 2000/53/EC (ELV). Limitations
PD IEC GUIDE 116:2018	Guidelines for safety related risk assessment and risk reduction for low voltage equipment

February 2019

BS ISO/IEC/IEEE 26511:2018	Systems and software engineering. Requirements for managers of information for users of systems, software, and services
BS ISO/IEC/IEEE 26515:2018	Systems and software engineering. Developing information for users in an agile environment
PD ISO/TR 22100-4:2018	Safety of machinery. Relationship with ISO 12100. Guidance to machinery manufacturers for consideration of related IT security (cyber security) aspects
BS EN 60335-2-29:2004 + A11:2018	Household and similar electrical appliances. Safety. Particular requirements for battery chargers
IEC 62087-7:2018	Audio, video and related equipment. Methods of measurement for power consumption. Computer monitors

Compliance Calendar

What's happening in the Compliance world in the next few months

January 2019

MON	TUE	WED	THU	FRI	SAT	SUN
	1	2	3	4	5	6
7	8	9	10	11	12	13
14	15	16	17	18	19	20
21	22	23	24	25	26	27
28	29	30	31			

February 2019

MON	TUE	WED	THU	FRI	SAT	SUN
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15 A	16	17
18	19	20	21	22	23	24
25	26	27	28			

A New EMC Directive standards must be used:

- EN 55011:2016, (replaces EN 55011:2009 + A1:2010)

March 2019

MON	TUE	WED	THU	FRI	SAT	SUN
				1	2	3
4	5	6	7	8	9	10
11	12	13	14	15	16	17
18	19	20	21	22	23	24
25	26	27	28	29	30	31

April 2019

MON	TUE	WED	THU	FRI	SAT	SUN
1	2	3	4	5	6	7
8	9	10	11	12	13	14
15	16	17	18	19	20	21
22	23	24	25	26	27	28
29	30					