

COMPLIANCE

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European standards being withdrawn

Other standards being withdrawn Lists of European Harmonised Standards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



4 weeks to go (maybe)

Standards being withdrawn (see standards watch)

· within 1 year

European Standards none identifiedOther 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



New standard

EN 61000-4-5:04 + A1:17

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European standards being withdrawn

The following standards are being withdrawn, at which time they will no longer provide a presumption of conformity for CE marking:

Old standard

Within 12 months Date

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

Subject

EMC

European harmonised standards are regularly updated

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

Other standards being withdrawn

EN 61000-4-5:2014

Within 12 months

08 Sep 2020

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:





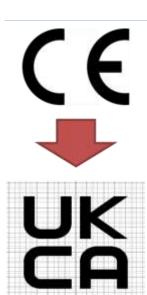
Brexit



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	28	
LVD	Exit) Regulations 2019	23	
EMC		20	
RoHS	The Waste (Miscellaneous Amendments) (EU Exit) (No. 2)	18	
WEEE	Regulations 2019		
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

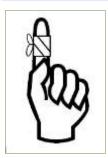
Guidance on controls of steels (except chrome plated products) and cast irons for RoHS & ELV

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
- 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 Fa

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			

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					

- A New EMC Directive standards must be used:
 - EN 55011:2016, (replaces EN 55011:2009 + A1:2010)