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OFC01504 – v1 – 24.11.2020 – Approval Level 1



# 'UK Conformity Assessed' marking: the UKCA mark

## UK Approvals in the case of a No-Deal Brexit



## European Union (Withdrawal Agreement) Act 2020

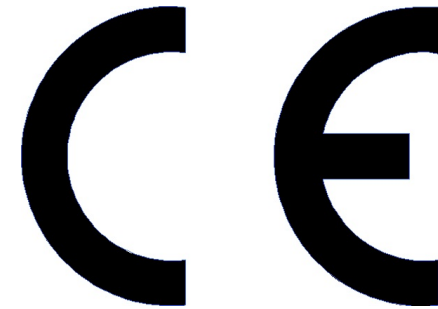
- 11pm on 31<sup>st</sup> December 2020
- European legislation will be turned into UK legislation
  - Directives (UK Statutory Instruments)
  - Regulations
- Minor amendments (references etc.)
  - Member States → United Kingdom
  - European Commission → Secretary of State
  - CE mark → UKCA mark



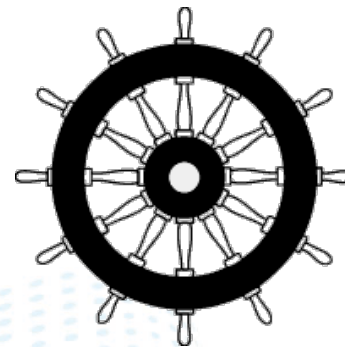
# UKCA Marks



Replaces



Replaces





# UK Bodies and Standards

- UK Notified Bodies will become UK Approved Bodies
  - Same scope
  - Same number: probably AB0338 or UK0338
  - Same accreditation (UKAS)
  - Approved to carry out same procedures / approvals under UK legislation
- EU Harmonised Standards will become 'Designated' Standards
  - Initially, same list as EU
  - Divergence will depend on sector / consultation
- Recommendations / Guidance / support structure
  - Sector-by-sector adoption
  - No concrete proposals in our sectors



# Placing on UK mainland market – 1<sup>st</sup> January 2021

- UK mainland market – England, Scotland and Wales
- UKCA mark and CE mark both accepted
- UKNB certificate = UKCA mark
  - Files not transferred to EU27 = must use UKCA mark
  - Copy of file/certificate kept by UKNB = can use UKCA mark
- CE / Wheelmarked product accepted by UK for 1 year
  - Products with EU27 NB certificates
  - Products with Files transferred from a UKNB to EU27 NB



# Placing on UK mainland market – 2022

- If no deal, then only UKCA mark accepted
- CE / Wheelmarked products already on UK market can be distributed
  - imported / manufactured and placed on UK market before end of 2021
- UK approvals will be required
  - UK Approval Body and UK Approval Certificates
  - PPE / MED Module B Type examination
  - CPR System 1 / 2+ Factory Production Control audits and certificates
  - PPE / MED QMS Module D/E audits
  - PPE / MED Modules C2/F Selection
  - CPR System 3 will require UK test reports



# Placing on Northern Ireland market – 1<sup>st</sup> January 2021

- Northern Ireland protocol
- No border with Ireland but also unfettered access to UK market
- Northern Ireland accepts CE mark from 2021 onwards
- UKCA mark will NOT be accepted
- Products certified by UK Approved Bodies marked “CE + UKNI”
- “CE + UKNI” acceptable only in NI, not accepted in EU or UK





# The Future of approvals for BTTG® & Shirley®

- Shirley Technologies Limited
  - UK Approved Body 0338
- Shirley Technologies (Europe) Limited
  - Ireland: Notified Body XXXX
- If no divergence in legislation / procedures / standards:
  - Two applications
  - One certification procedure (audit, type-examination)
  - Two certification decisions
  - Two certificates