VEDP

UKCA Marking Information Brief

JUNE 2022

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What is the UKCA Mark?

Following its departure from the EU, the UK has developed a series of its own trade markings, in order to facilitate the harmonization of standards and the free flow of goods on its domestic market.

The UKCA, or UK Conformity Assessed as it is more formally known, is a new product marking that has been introduced, and serves as a mechanism for demonstrating to consumers, that certain goods are compliant with the relevant UK legislation pertaining to Health, Safety and Environmental Protection. The UKCA mark is applicable to all of the goods that were previously covered under the EUs CE Marking scheme, and essentially serves the same purpose of highlighting regulatory conformity from the manufacturers.

However, The UKCA marking only convers goods that are to be circulated within Great Britain and cannot be used for Northern Ireland. Instead, a separate UKNI mark may be used alongside the CE mark to demonstrate conformity, as Northern Ireland remains both in the UK and inside the EUs single market for goods.

What is Covered by the UKCA Mark?

Therefore, to ensure compliance, many exporters will have to revaluate their packaging when looking at the UK Market, as they will need to take this new compliance labelling into consideration. As previously mentioned, the UKCA mark covers all goods that were previously subject to the CE Marking. This is simply to demonstrate that they meet the requirements of each of the application regulations, in order to be sold on the UK market. Products that may need the marking include:

- Toys
- Measuring Instruments
- PPE
- Gas Appliances
- Machinery
- Equipment
- Electrical equipment and various electronic components
- Restricted or Hazardous Substances

Products with Special Rules:

- Medical devices
- Rail interoperability
- Construction products
- Civil explosives

For the full list, please see the UK website here.

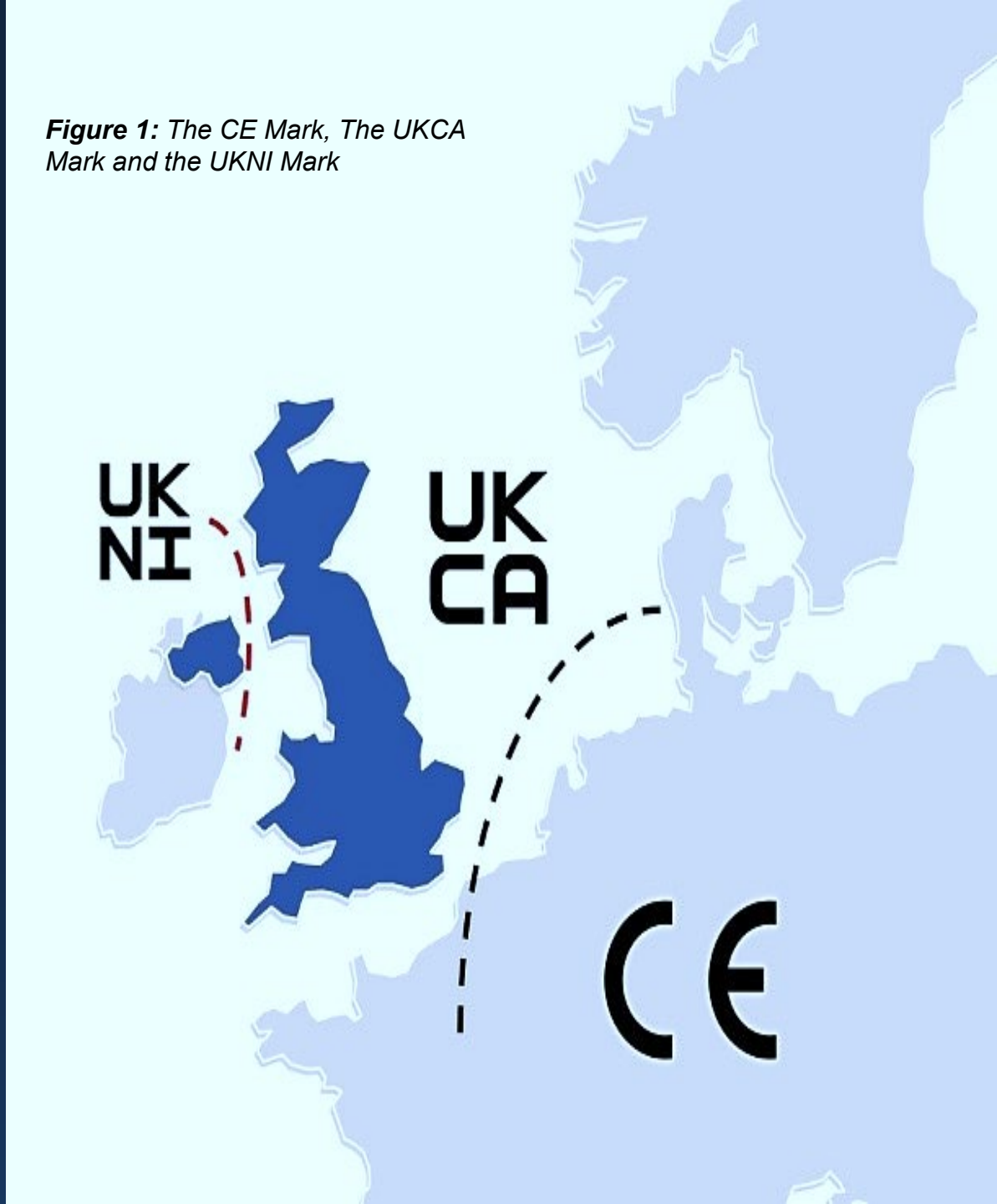


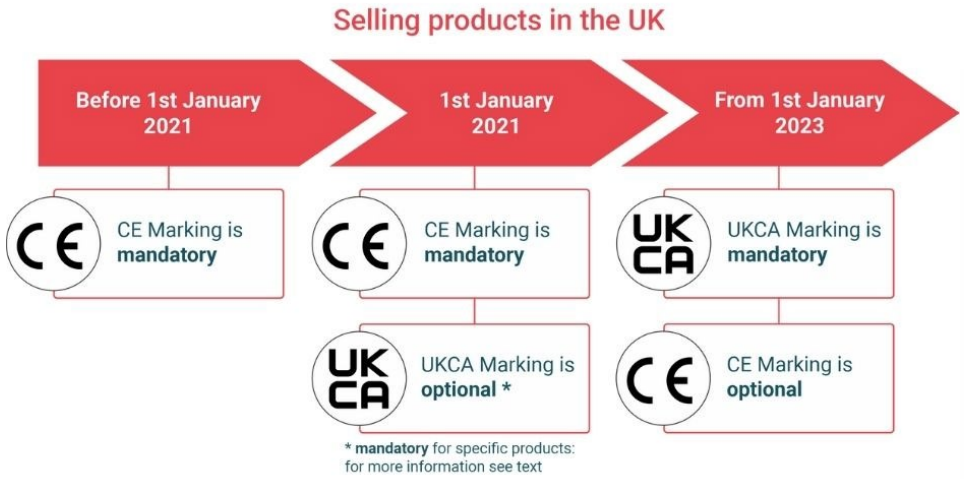
Figure 1: *The CE Mark, The UKCA Mark and the UKNI Mark*

When does the UKCA Mark come into effect and what about pre-existing products?

The regulation itself which requires that goods display the UKCA Marking does not come into effect until the 1st of January 2023, meaning that until that date, companies will be able to continue to use the traditional CE marking to demonstrate conformity.

Furthermore, The UKCA Marking does not impact products that were fully manufactured and placed on the market prior to the 1st of January 2023, meaning that pre-existing goods already in circulation are exempt from this legislation and do not need the new marking retrospectively applied.

1. CE marking will continue to be recognized in Great Britain until 30 June 2023
2. Certificates issued by EU-recognized Notified Bodies will continue to be valid for the Great Britain market until 30 June 2023
3. The EU no longer recognizes UK Notified Bodies
4. UK Notified Bodies cannot issue CE certificates - and have become UK Approved Bodies



What do Manufacturers need to do?

There are two ways that manufacturers can demonstrate conformity and therefore affix the label on their products.

The first of which entails a basic “self-assessment”, meaning that, for certain product categories, manufacturers can simply assess whether they meet the relevant standards themselves, independently, and if successful, they are free to draft their own declaration of conformity and affix the UKCA Marking to their goods (See Table 1.).

Alternatively, some products require testing by an independent third-party, who must assess for conformity to requirements prior to providing the declaration to the manufacturer. In this instance, companies have to approach certified assessors, a list of which can be found here.

Process to obtaining the UKCA mark

- **Find the directive(s) that applies to your product (UK MDR)**
- **Know the essential requirements for your product**
- **Determine if you need third-party assessment (Only medical devices of the lowest risk class do not need to involve a 3rd party assessor)**
- **Assess Product Conformity**
- **Create and maintain technical documentation (This information should cover every aspect relating to conformity)**
- **Declaration of Conformity & affixing the UKCA mark**

When is Self Assessment Permitted?

Table 1: What areas allow for self assessment.

Legislative areas where self-declaration of conformity for UKCA marking is permitted	
Legislation	**Scope of products which can be self-declared**
Electromagnetic Compatibility Regulations 2016	*All products*
Toy (Safety) Regulations 2011	*Products where all essential requirements are covered by designated standards and the manufacturer has applied these standards*
The Restriction of the Use of Certain Hazardous Substances in Electrical and Electronic Equipment Regulations 2012	*All products*
Medical Devices Regulations 2002	*Some Class I devices*
Radio Equipment Regulations 2017	*All products except where designated standards for regulation 6 (2) either do not exist or have not been applied by the manufacturer.*
The Pressure Equipment (Safety) Regulations 2016	*Category I pressure equipment*
Construction Products Regulations (Regulation (EU) 305/2011 as brought into UK law and amended)	*Products within scope of System 4*
Recreational Craft Regulations 2017	*Certain categories of recreational craft as specified in the legislation*
The Electrical Equipment (Safety) Regulations 2016	*All products*
The Supply of Machinery (Safety) Regulations 2008	*Any machine which is not in Schedule 2, Part 4 of the Regulations.* *Any machine that is in Schedule 2, Part 4 where the requirements of all relevant designated standards have been applied in full and where those standards cover the applicable essential requirements.*
The Equipment and Protective Systems Intended for Use in Potentially Explosive Atmospheres Regulations 2016	*Equipment-group II, equipment category 3*
Personal Protective Equipment Regulations (Regulation (EU) 2016/425 as brought into UK law and amended)	*Category I personal protective equipment*

What is included in the declaration of conformity?

The UK Declaration of Conformity is a document which must be drawn up for most products lawfully bearing a UKCA marking. It is recommended that manufacturers have a separate UK Declaration of Conformity to their EU Declaration of Conformity. The declaration may vary depending on the product itself, but typically includes:

1. The Product, its Batch and Serial Number
2. The Name and Address of the Manufacturer or authorised representative
3. Description of the product
4. A statement that the product does in fact conform to the relevant legislation
5. Reference to said legislation or standard
6. Where applicable, reference to the approved third-party body which undertook assessment
7. Signature of the manufacturer

The UK Declaration of Conformity also must be available to enforcing authorities on request.

To see the full declaration, visit here.

Jobskin Ltd

Version: 1.0
Date: 13/05/2021

EU Declaration of Conformity

Declaration of Conformity

for Compression Garments for Therapy Management

Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 concerning Medical Devices

The undersigned declares that the products described in this document meet the Council provisions that apply to them and the CE Mark may be affixed.

General Product Name:	Premium, Classic, Interim and Post-Surgical Compression Garments
Legal Manufacturer: (Name on Label)	Jobskin Ltd 13a Harrington Mill, Leopold Street, Long Eaton, Nottingham, NG10 4QG United Kingdom
Manufacturers SRN:	Not Yet Available
Basic UDI-DI:	506059893TF20006F
Variants:	As per Appendix II (This document) – Product Listing/Schedule
Intended Purpose:	The purpose of the Premium, Premium Interim and Classic Pressure garments is to manage problem scars. The garment provides a compression on areas of raised hypertrophic scarring to flatten, soften and reduce scarring and erythema of the scar and aid the natural scar maturation process.
MDR Classification:	Class I [Rule 1]
Notified Body:	Not Applicable
EC Certificate:	Not Applicable
EU Authorised Representative:	Advena Limited. Tower Business Centre, 2nd Flr., Tower Street, Swatar, BKR 4013 Malta.
EU Authorised Representative SRN:	MT-AR-000000234
Medical Device Regulation Assessment Route:	Not Applicable

Name Debra Wright **Position** Technical Business Development Manager

Signed DWright **Date** 13/05/2021

Who is the natural and legal person with responsibility for the design, manufacture, packaging and labelling before the device is placed on the market under this manufacturer's name regardless of whether these operations are carried out by the manufacturer or on his behalf by a third party.

Affixing the UKCA Mark

Companies must apply the UKCA marking to the product itself or to the packaging. The UKCA marking must be clearly visible and legible. Rules for affixing the UKCA Mark can be found here.

You must make sure that:

1. If you reduce or enlarge the size of your marking, the letters forming the UKCA marking must be in proportion to the version set out below
2. The UKCA marking is at least 5mm in height – unless a different minimum dimension is specified in the relevant legislation
3. The UKCA marking is easily visible, legible (from 1st January 2023 it must be permanently attached)

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