Discussion paper on the application of the UKCA marking on medical devices identified with GS1 standards

Purpose

This paper aims at providing recommendations on the identification of medical devices using GS1 standards and the application of the UKCA (UK Conformity Assessed) marking. It is important to acknowledge that the recommendations in this paper are provided taking into account the regulatory requirements of January 2021, and that these recommendations would need to be reassessed in a different regulatory context.

As articulated in the GS1 General Specification, Regulatory requirements around the globe will always supersede GS1 standards when applied to healthcare products.

Audience

The main target audience for this paper are the healthcare brand owners assigning GTINs (UDI-DIs) to medical devices on the market in Great Britain (England, Wales and Scotland).

Scope

This paper focuses on regulated medical devices in the context of the EU CE marking and of the UKCA marking requirements.

Introduction

As a result of the Brexit, the UKCA marking[1] is a new product conformity marking that is used for medical devices and other goods being placed on the market in Great Britain. It covers most devices which previously required the CE marking in the EU.
For devices placed on the Northern Ireland market by a manufacturer based in Great Britain or manufacturers choosing a "UK Notified Body" for mandatory third-party conformity assessment, a UKNI marking (conformity marking for products placed on the market in Northern Ireland) is required in addition to the EU CE mark. The UKNI mark must be coupled with the EU CE mark if placed on the market in Northern Ireland. However, the UKNI mark cannot be used on devices placed on the EU market.

Until 30 June 2023, for most devices, the economic operators have the option to affix the UKCA marking on a label of the device. From 1 July 2023, the UKCA marking must be applied on the device package labels. The UKCA marking can be used together with the CE marking.

Issue statement

According to the GS1 Healthcare GTIN Allocation Rules, "a change to packaging to add a new, or remove an existing certification mark (e.g., European Certification Mark CE), that has significance to regulatory bodies, trading

1 For a complete description of the UKCA mark requirements for medical devices, please refer to Medical Devices Regulations 2002 (SI 2002 No 618, as amended) (UK MDR 2002): Part II of the UK MDR 2002 on general medical devices, Part III of the UK MDR 2002 on active implantable medical devices, Part IV of the UK MDR 2002 on in vitro diagnostic medical devices (IVDs).

partners (supply chain) or to the end consumer, requires assignment of a new GTIN." This means that, in principle, every CE marked devices supplied to the market in Great Britain with an additional UKCA marking would need a new GTIN, regardless of whether the CE marking remains on the pack.
However, it should also be noted that when a certification mark is added to enable sales in a new country/market it has no impact on countries/markets where the product was previously sold – in this case there is no need to allocate a new GTIN in the scenario above.

Brand owners are responsible for internal control of their inventory and any return systems. It is important that such systems, as well as phase-in & phase-out logistic management, can distinguish between 'old' and 'new' product. When this can be effectively achieved by using other identification which is satisfactory to all trading partners , there is no need to allocate a new GTIN in this scenario, however, the external supply chain must be unaffected regarding expected functionality.

Recommendation

To ensure the harmonised implementation of the UKCA marking requirements while aligning with the industry practices/plans, there is no need to allocate a new GTIN to medical devices supplied to the market in Great Britain, assuming the addition of UKCA to an existing CE Marked product. However, it is critical to ensure that the medical devices which have the new conformity marking can be differentiated from those that do not, normally achieved using a new GTIN Allocation or other product identification, in order to ensure patient safety and supply chain management between all trading partners.

The GS1 Healthcare GTIN Allocation Rules states that "it should be noted that when a certification mark is added to enable sales in a new country/market it has no impact on countries/markets where the product was previously sold – in this case there is no need to allocate a new GTIN".

Following the Brexit, Great Britain can be in that context, considered as a new market, with new regulations and market specifications.