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Medical devices: updated Borderline Manual released

Introduction

The European Commission has updated the Manual on Borderline and Classification in the Community Regulatory Framework for Medical Devices (the "Borderline Manual"). This is intended to help manufacturers determine whether their product falls within the definition of a medical device laid down in the Council Directive 93/42/EEC concerning medical devices (the "MDD").

A product will generally fall within the definition of a medical device if it has a medical purpose and if the product functions primarily in a way that is neither metabolic, immunological or pharmacological. Determination of whether a product has a medical purpose will be based on its intended purpose.

The MDD includes several rules for the exact classification of a medical device. The Borderline Manual provides guidance for a broad range of "borderline" products like water filters, shoe covers, radiation shields, fluid collection bowls and hand disinfectants.

The European Commission has updated the Borderline Manual with guidance for the classification of three products: automated external defibrillator storage units, lubricants for the alleviation of vaginal dryness and medication decisions support software.

Updated products

Automated external defibrillator storage units

Automated external defibrillator ("AED") storage units are available in an increasing number of settings and locations. The Borderline Manual provides guidance for the classification of a storage unit of an AED. Storage units can be classified as Class I accessories to a medical device if they're intended to maintain the required environmental conditions for the AED.

Article 1.2 (b) of the MDD provides that an accessory to a medical device is

> "An article which whilst not being a device is intended specifically by its manufacturer to be used together with a device to enable it to be used in accordance with the use of the device intended by the manufacturer of the device."

The Borderline Manual provides that, if the AED storage unit is not intended to maintain the required environmental conditions for an AED to perform as intended, the storage unit should not be qualified as an accessory to a medical device.

Water- or silicone-based lubricants

The Borderline Manual provides that water- or silicone-based lubricants intended for the alleviation of vaginal dryness during sexual intercourse should be qualified as medical devices. As invasive medical devices intended for short-term use, they should be classified in Class I or IIa, depending on how long they are expected or likely to remain in the body.

Medication decision-support software

There's been an exponential increase in software designed to be used by healthcare professionals to optimise a patient's medicinal product intake. Medication decision-support software gathers data on the medicinal products that will be administered. It could, for example, identify possible contraindications, provide warnings about interactions of medicinal products and/or suggest options for treating previously untreated conditions.

The Borderline Manual provides that medication decision-support software falls within the definition of a medical device.[23] This is because the medication decision-support software is used for the purpose of prevention, monitoring, treatment or alleviation of a disease. The prevention, monitoring, treatment and alleviation of a disease is one of the possible purposes of a medical device provided by Article 2 (a) MDD.

23 Software classified as a medical device is commonly referred to as "medical device standalone software".

Comment

Manufacturers of the abovementioned medical devices should assess whether they need to take any steps to ensure regulatory compliance.

Manufacturers that have not considered the abovementioned products to be medical devices should conduct a conformity assessment procedure. Depending on the classification of the medical device the manufacturer will have to involve a Notified Body in the conformity assessment procedure.

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