Medicines & Healthcare products Regulatory Agency

MHRA
Regulating Medicines and Medical Devices

Decision document on baby breathing / movement monitors

February 2021

Contents

1. Introduction

The MHRA is aware of a range of baby breathing/movement monitors available for sale on the UK market. These products monitor the breathing, heart rate, movement and/or blood oxygen saturation levels of a baby, in various ways. Some products provide varying forms of alert to the parent or to the baby itself by trying to rouse the child. Many of these products are marketed as general consumer goods. Some of these products, in MHRA's view, meet the legal definition of a medical device and accordingly are required to undergo a conformity assessment before being CE marked as medical devices in accordance with the Medical Devices Regulations 2002.

Supplying a medical device without a CE mark is, subject to very limited exceptions set out in the Medical Devices Regulations 2002, likely to be an offence under section 12 of the Consumer Protection Act 1987.

2. Purpose

The purpose of this document is to set out MHRA's approach to the regulation of baby breathing / movement monitors.

3. Overview

MHRA do not consider conventional audio-visual baby monitors to be medical devices on the basis they are only intended to enable a parent to be aware of whether the baby is awake or asleep. In contrast, products that monitor vital physiological parameters of the baby are more likely to be considered medical devices by MHRA. For example, those that monitor respiration and heart rate.

4. Legal definition of a medical device

The definition of a medical device for the purposes of the Medical Device Regulations 2002 is set out in Annex 1 to this document. MHRA is of the view most baby breathing/movement monitors are captured by the first and or third indent of this legal definition, that is, they are preventing or monitoring a disease or investigating a physiological process.

5. MHRA's guidance on legislation: Borderlines with medical devices - May 2016

The guidance contains information pertinent to manufacturers of baby breathing/movement monitors. It refers to words and phrases that can be inferred by MHRA as contributing towards a medical claim. It includes information about MHRA's attitude towards the use of general disclaimers, testimonials, anecdotal quotes etc. See annex 2.

6. MEDDEV 2.4/1 Guidelines for the classification of medical devices

MEDDEVs are sets of guidelines relating to questions of application of EU Directives on medical devices. MEDDEV 2.4/1 has been revised after consultation with various interested parties (e.g. Competent Authorities, Commission services, industry and other stakeholders) and therefore this document reflects a consensus view on the classification of medical

devices. MEDDEV 2.4/1 contains guidance for the application of the classification rules for medical devices as set out in Annex IX of Directive 93/42/EEC, as amended. It is for the national Competent Authorities and national Courts to take legally binding decisions on a case-by-case basis.

MEDDEV 2.4/1 indicates products monitoring blood oxygen saturation levels and apnoea monitors are likely to be medical devices. See Annex 3.

7. Representations made by manufacturers

In December 2019 the MHRA conducted a review of baby breathing / movement monitor products available on the UK market. The focus of the review was predominantly to determine whether such products should be regulated as medical devices. The review looked at the manufacturer's intention for the product as defined in their labelling, instructions for use and promotional material and its mode of action in conjunction with the definition of a medical device as stated in the Medical Device Regulations 2002.

Manufacturers of products within scope of the review were invited to provide written representations as to the regulatory status of their products. Further, manufacturers were invited to provide a detailed justification and rationale as to why their products are / are not medical devices.

The MHRA has taken into consideration the representations put forward by manufacturers to help inform its future regulatory approach to baby breathing/movement monitors.

8. Manual on borderline and classification in the Community Regulatory framework for medical devices' from the Medical Devices Expert Group on Borderline and Classification.

The Medical Devices Expert Group on Borderline and Classifications working group, which is an EU working group comprised of experts from all EU member states, EFTA Members and other stakeholders has determined that many baby breathing/movement monitors are medical devices on the basis of the first and third indents of the definition of a medical device. They may be diagnosing or monitoring a disease (sleep apnoea or Sudden Infant Death Syndrome) or investigating a physiological process (monitoring breathing, heart rate, oxygen saturation etc). See annex 4.

9. Consumer research looking into the UK consumers' perceptions and expectations as regards baby monitors. Commissioned by MHRA and completed by an independent market research agency.

The core aims of the research was to explore awareness of and attitudes towards baby breathing/movement monitors as a group and individually; and in particular why potential customers might consider buying them; what they might use them for; and their expectations of how they should or would be regulated. The findings have been used to inform MHRA's assessment of whether products in scope met the definition of a 'medical device'. See annex 5.

10. Illustrative scenarios

MHRA have drafted some scenarios which will help manufacturers understand if their product is likely to fall within scope of MHRA's interpretation of the definition of a medical device. See annex 6.

11. MHRA's regulatory approach to baby breathing/movement monitors

In forming its regulatory approach, MHRA have: considered the legislation, considered the views of manufacturers impacted, consulted other EU regulators, consulted UK consumers, considered MEDDEV and MHRA guidance documents pertinent to the issue at hand.

In summary, products that monitor vital physiological parameters of the baby are likely to be considered medical devices by MHRA. For example, those that monitor respiration and heart rate.

Where evidence exists indicating the appropriate regulatory pathway for placing products on the UK market has not been followed, MHRA will make contact with the entity concerned outlining our concerns and requesting remedial measures are put in place to bring an end to the non-compliance and any unnecessary risk to health or safety the device may present. Should remedial measures not be taken, MHRA may need to resort to taking formal enforcement action using its statutory powers under the Medical Devices Regulations 2002, General Product Safety Regulations 2005 and / or Consumer Protection Act 1987, as appropriate.

Annex 1 - Legal definition of a medical device

Definition of a medical device

The definition of a medical device (for the purposes of the Medical Device Regulations 2002, which transpose Directive 93/42 on medical devices) reads:

"'medical device' means any instrument, apparatus, appliance, software, material or other article, whether used alone or in combination, including the software intended by its manufacturer to be used specifically for diagnostic and/or therapeutic purposes and necessary for its proper application, intended by the manufacturer to be used for human beings for the purpose of:

— diagnosis, prevention, monitoring, treatment or alleviation of

disease,

—diagnosis, prevention, monitoring, treatment, alleviation of or compensation for an injury or handicap,

— investigation, replacement or modification of the anatomy or of

a physiological process,

— control of conception,

and which does not achieve its principal intended action in or on the human body by pharmacological, immunological or metabolic means, but which may be assisted in its function by such means;"

Annex 2 - MHRA's guidance on legislation: Borderlines with medical devices - May 2016

MHRA updated its guidance document in May 2016. The below excerpt is the annex to the guidance which contains pertinent information for manufacturers of baby breathing/movement monitors that might meet the legal definition of a medical device.

Appendix: Words and phrases

The words and phrases listed below are all likely to have contributed to a determination by the MHRA that the product they were associated with was a medical device. In some cases specific wording may imply that a product would be considered as a medicinal one (consult appendix 1 of the MHRA's 'A guide to what is a medicinal product' for details).

Aids treatment
Alleviates
Avoids
Can benefit those who suffer from...
Clinically proven
Combats
Compensates for …
Counteracts
Cure/cures
Diagnoses / assists diagnosis
Eases symptoms
Eliminates
Heals
Help/help with...
Investigation
Monitors
Pain relief / relief from pain
Prevents ……
Protects against...
Repairs
Stops
Traditionally used for....
Treats/clears infestations
Treats/Treatment/Treating

Although such words or phrases may contribute to such a determination, the intended and implied meaning of the words used will be considered in context with relation to the product concerned and its intended purpose. This is not an exhaustive list and should not be considered as such.

It should be noted that general disclaimers (for example 'this product is not a medical device') are not acceptable if medical claims are made or implied elsewhere in the product labelling or associated promotional literature.

Anecdotal quotes and testimonials are considered to be implied claims by the manufacturer if they are repeated in product literature.

Annex 3 - MEDDEV 2.4/1 Guidelines for the classification of medical devices

The following excerpt from MEDDEV 2.4/1 indicates products monitoring blood oxygen saturation levels and apnoea monitors are likely to be medical devices.

Under classification rule 10 for active diagnostic medical devices the fourth indent gives examples of active diagnostic devices intended for monitoring vital physiological processes as follows:

unless they are specifically intended for monitoring of vital physiological parameters, where the nature of variations is such that it could result in immediate danger to the patient, for instance variations in cardiac performance, respiration, activity of CNS in which case they are in Class IIb.

- Intensive care monitoring and alarm devices (e.g. blood pressure, temperature, oxygen saturation)
- Biological sensors
- Blood gas analysers used in open heart surgery
- Cardioscopes
- Apnoea monitors, including apnoea monitors in home care

Vital physiological processes and parameters include, for example respiration, heart rate, cerebral functions, blood gases, blood pressure and body temperature.

The MEDDEV also clarifies that medical devices intended to be used for continuous surveillance of vital physiological processes in anaesthesia, intensive care or emergency care are in Class IIb, whilst medical devices intended to be used to obtain readings of vital physiological signals in routine check-ups and in self-monitoring are in Class IIa.

It should be noted that the classification MEDDEV document only provides examples of medical devices in each classification rule and is not an exhaustive list.

Annex 4 - Manual on borderline and classification in the Community Regulatory framework for medical devices' from the Medical Devices Expert Group on Borderline and Classification.

The Medical Devices Expert Group on Borderline and Classifications working group, which is an EU working group comprised of experts from all EU member states, EFTA Members and other stakeholders has determined that many baby breathing/movement monitors are medical devices on the basis of the first and third indents of the definition of a medical device. They may be diagnosing or monitoring a disease (sleep apnoea or Sudden Infant Death Syndrome) or investigating a physiological process (monitoring breathing, heart rate, oxygen saturation etc).

The following excerpt from the manual on borderline and classification in the community regulatory framework for medical devices provides a useful indication as to the appropriate regulatory status of products that stimulate babies in order to prevent life-threatening events such as apnoea and Sudden Infant Death Syndrome.

Manual on borderline and classification in the community regulatory framework for medical devices:

8.14. Movement monitor for babies

- Background

The manufacturer claims that this product is recommended for all babies, especially during their most vulnerable first 6 months, to help guard against life-threatening events such as Apnoea and Sudden Infant Death Syndrome (SIDS or Cot Death).

A little vibrating motor is used to stimulate babies in neonatal wards that suffer apnoea episodes and can indicate if they are rhythmic or general movements. If the baby becomes dangerously inactive, this product will provide a small tactile stimulation even before human intervention. If breathing effort stops, slows down too much or becomes too shallow the built-in stimulator will gently stir baby to breathe, failing which a loud alarm will alert the nearest adult and consequently should be help by a doctor. The problem is to know whether this product could be considered as a general product or as a medical device or as an active medical device.

- Outcome

This product is intended to help preventing life-threatening events such as apnoea and Sudden Infant Death Syndrome (SIDS or Cot Death). Taking this medical purpose into account this product fulfils the definition of a medical device.

This product is to be connected with a source of electrical energy and could then be considered as an active medical device. According to classification rule 10, this product should be classified as Class IIb medical device.

Annex 5 - Consumer research looking into the UK consumers' perceptions and expectations as regards baby monitors. Commissioned by MHRA and completed by an independent market research agency.

Baby Monitors:
Consumer Perceptions and Expectations
Research for the Medicines and Healthcare products Regulatory Agency
April 2020

The core aims of the research was to explore awareness of and attitudes towards these products as a group and individually; and in particular why potential customers might consider buying them; what they might use them for; and their expectations of how they should or would be regulated. The findings would be used to inform MHRA's assessment of whether or not each of the products met the definition of a 'medical device'.

Key conclusions from the research are listed below.

- Deliberately or not, **the products all imply one or more medical functions**: that is, they are designed to monitor the baby's health and well-being and alert the parent or caregiver if the baby's vital signs give cause for concern, or even to intervene automatically to restart the baby's breathing; and this is the understanding that parents are likely to gain from the manufacturers' websites.

- Although parents also respond to other features such as design, price and ease of use, the products are mainly of interest because **they offer to identify, monitor or in some cases treat a medical condition.** They are also assumed to be designed mainly for premature babies, those with a medical condition or those with a higher risk of apnoea or SIDS.

- Parents **expect these products to be regulated to a high degree**, in part because of their medical functions, in part because they are attached to the baby or placed in the cot.

- Also, parents **assume that these products are regulated as medical devices** (that is, to the same standards as an equivalent product used in a healthcare setting) and that they would not be allowed to be put on the market without being tested and certified, and as a consequence they do not seek to check the regulatory status of the products themselves.

- Parents **were confused and in some cases angered by the disclaimers** that state the products are not medical devices or should not be used as medical devices.

Annex 6 - Illustrative scenarios

MHRA can only assess each baby breathing/movement monitor individually and on a case by case basis given the significant variation in manufacturers' claims and intention for their product, labelling, instructions for use, promotional material and its mode of action. However, there are illustrative scenarios which can be set out here which will help manufacturers understand if their product is likely to fall within scope of MHRA's interpretation of the definition of a medical device.

Scenario 1

For all intents and purposes, device A is a medical device i.e. the labelling, instructions for use, promotional material and its mode of action all strongly indicate the product is indeed a medical device. The manufacturer of device A simply asserts by way of a disclaimer in their promotional material that the product is not a medical device and thereby exempt from adhering to and being regulated by the medical device regulations.

MHRA's viewpoint on scenario 1 is that the manufacturer's stated view of their product is not solely determinative as to whether their device is or is not a medical device. Based on the surrounding circumstances e.g. the labelling, instructions for use, promotional material, its mode of action and manner of use as perceived by the consumer, it is possible for an objective observer such as the MHRA or an averagely informed consumer to view the product as a medical device.

Scenario 2

Device B's promotional materials state that it monitors breathing or movement and that in the event breathing or movement stops, the product will emit an alarm notifying the parent to take action.

MHRA's viewpoint on scenario 2 is that breathing is a vital physiological process. Where a product is monitoring breathing, the absence of which is indicated by an alarm, MHRA considers the monitoring of the physiological process as a medical claim, since the product is investigating a physiological process (i.e. detecting the lack of breathing) for a medical purpose.

Where manufacturers' promotional materials claim their products monitor movement and this movement is clearly associated with the area around the tummy of a baby, MHRA are of the view this form of movement monitoring is akin to monitoring breathing.

Scenario 3

Device C offers functionality to monitor the baby's breathing, emitting an alarm if no movement is detected after 20 seconds to alert the parent to take action. In amongst the manufacturer's promotional materials on its website are disclaimers asserting the product is not a medical device and should not be used for a medical purpose. On the same

manufacturer website, customer testimonials report on how they used the device to prevent Sudden Infant Death Syndrome and consequently their child still alive.

MHRA's viewpoint on scenario 3 is that Sudden Infant Death Syndrome and sleep apnoea are diseases for the purposes of the definition of what constitutes a medical device as per the regulations. MHRA also consider that the manufacturer is in direct control of the testimonials they choose to promote on their website and those they do not. Such testimonials can be considered manufacturer promotional materials. Testimonials clearly indicating the parent used the device for a medical purpose and that is was effective in preventing a disease are likely to be considered medical claims by the MHRA.

Scenario 4

Device D's promotional materials make explicit reference to potential symptoms and causes of Sudden Infant Death Syndrome. Device D's promotional materials go on to explain how their device can provide a warning to the parent as to the potential onset of a Sudden Infant Death Syndrome related episode.

MHRA's viewpoint on scenario 4 is that Sudden Infant Death Syndrome is a disease for the purposes of the definition of a medical device. Where manufacturers' promotional materials explicitly reference the potential causes of Sudden Infant Death Syndrome and then go on to explain how their device can provide a warning to the parent as to the potential onset of a Sudden Infant Death Syndrome episode, enabling them to attend to the baby and take suitable remedial action, MHRA are likely to view such promotional materials as a medical claim.

Scenario 5

Device E offers a function to physically stimulate the baby if the device detects a lack of movement for a set period of time. After a further defined period of time, if inactivity continues despite the physical stimulation, an alarm will sound alerting the parent to take action.

MHRA's viewpoint on scenario 5 is that the product in question is intended to help prevent a life-threatening event such as apnoea and Sudden Infant Death Syndrome. Taking this medical purpose into account, it is likely the product fulfils the definition of a medical device.

Scenario 6

Device F's promotional materials state that it monitors oxygen saturation levels and/ or heart rate. In the event the baby's oxygen saturation levels and/ or heart rate fall outside a pre-set range, the device will sound an alarm, alerting the parent to take suitable action.

MHRA's viewpoint on scenario 6 is that monitoring a baby's blood oxygen saturation levels and or heart rate are activities considered to be monitoring of vital physiological process and / or vital signs, both of which would likely be considered a medical claim by the MHRA.