Poster Presentation: PAC Product Classification

...reducing avoidable harms

WOUND CARE TODAY CONFERENCE, MILTON KEYNES 2018

Does CE-ing really mean believing? Safe, effective, harm free care and the role of the Notified Body in CE marking powered pressure area care mattresses

Richard Forder. Head of Clinical Affairs, Talley Group Limited, UK

Introduction

It is a legal requirement for all medical devices sold in Europe to be CE marked, however, before CE marking their products, manufacturers must decide which medical device class it fits into (see Table 1).

Medical device classification is governed by a set of rules in the Medical Device Directive and relates directly to the potential risk posed by the device. Therefore higher risk devices are given a higher medical device classification (see Table 1) and it is this classification that dictates the level of regulation a product must meet to obtain (and maintain) its CE mark.

MEDICAL DEVICE CLASSIFICATION	GENERAL DESCRIPTION	LEGAL REQUIREMENT FOR AUDIT BY NOTIFIED BODY
Class I (low risk)	Non-invasive devices (i.e. a bed frame, walking aid, patient hoists, stethoscopes etc.)	No
Class IIa (low-medium risk)	Active therapeutic devices (intended to administer or exchange energy), invasive devices and dressings	Yes
Class IIb (medium risk)	Active therapeutic devices (intended to administer or exchange energy in a potentially hazardous way), invasive devices and dressings for extensive, complex wounds	Yes
Class III (high risk)	Implantable devices / pharmaceuticals	Yes

TABLE 1.
Medical device classification and Notified Body auditing requirements

CE marking medical devices

Are all medical devices subjected to stringent, independent regulation?

No. Manufacturers of Class I (low risk) devices 'self-certify' that their own products meet all legal and regulatory requirements and they CE mark the products themselves.

Neither the product Technical File (i.e. Risk Management File; Clinical Evaluation Report; Post-Market Clinical Follow-up; Biocompatibility; Essential Requirements checklist etc.) nor any safety or performance claims made by the manufacturer are ever independently audited (regulated) by a Notified Body. Therefore Class I devices are effectively unregulated and placed on the market without ever being formally assessed or reviewed.

Manufacturers of Class IIa, IIb and III devices CANNOT self-certify and must comply with all appropriate legal and regulatory requirements. All Technical File documentation and product claims of safety and performance are independently audited by a Notified Body BEFORE a product CE mark is granted and the product can be sold.

Financial implications

For clinicians unfamiliar with medical device regulations it is important to understand that involving a Notified Body and compiling all necessary documentation behind a Class IIa, IIb or III product requires significant financial investment from the manufacturer. This investment will often be reflected in the purchase, lease or rental costs for the device in question.

Powered PAC support surfaces classification

Most medical devices fit neatly into one specific device class, however, classification of powered pressure area care (PAC) support surfaces is open to interpretation.

Under current EU guidelines manufacturers must decide whether their powered PAC mattress is a 'Non-invasive device' (Rule 1) OR an 'Active device' (Rule 9). See Figure 1.

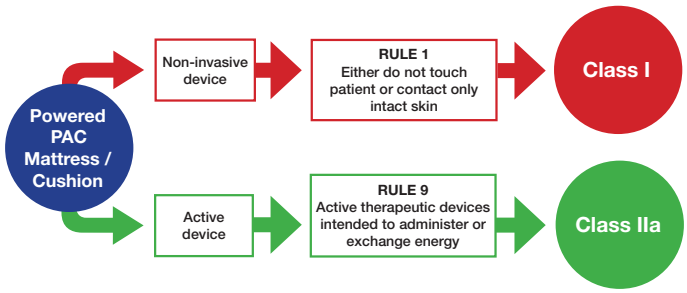

FIGURE 1.
Powered PAC mattress classification: Non-invasive vs. Active devices?

Manufacturers who decide their powered support surface is 'non-invasive' follow the unregulated Class I route for CE marking and simply 'self-certify' their own product as safe and effective (see Figure 2). Therefore the mattress is CE marked, sold and placed under patients without any independent external checking of Technical File documentation or manufacturers claims of safety or performance.

Manufacturers who decide their powered support surface is an 'active therapeutic device' follow the highly regulated Class IIa route for CE marking.

Class IIa support surfaces are only granted a CE mark once manufacturers claims of safety and performance and all Technical File documentation behind the product is audited and approved by a Notified Body (see Figure 2). The Notified Body regularly re-audits the product throughout its lifecycle to ensure claims remain accurate and documentation current.

The role of the Notified Body

A Notified Body is only involved in certifying, CE marking and regulating Class IIa, IIb and III medical devices. Unregulated Class I devices have no Notified Body involvement.

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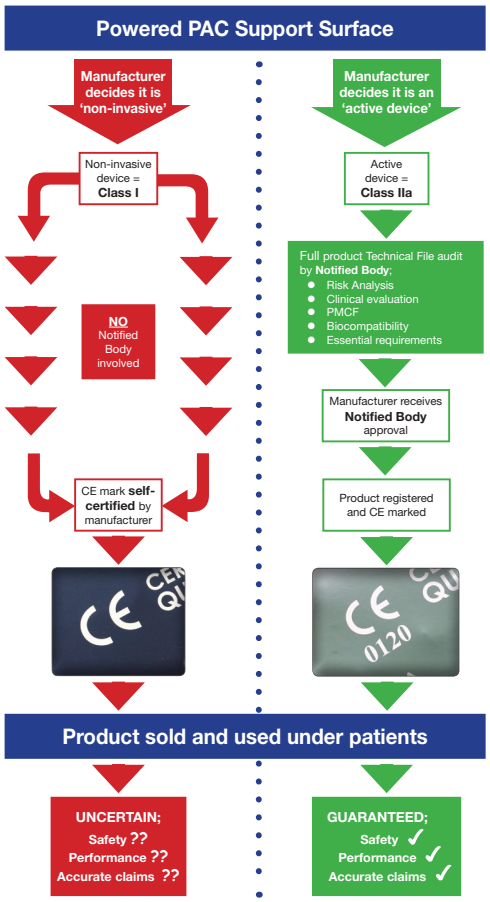

FIGURE 2.
CE marking routes for Class I and Class IIa medical devices

A Notified Body is an organisation which operates in a non-discriminatory, transparent, neutral, independent, and impartial manner. Its role is to conduct a conformity assessment as part of the CE marking process. For powered Class IIa support surfaces this requires:

1. A comprehensive on-site audit of the manufacturer's Quality Management System and facility, including review of the manufacturing process, systems, controls, material handling etc. The audit is carried out to ISO 13485 which demonstrates a manufacturers commitment to medical device quality and safety.
2. Prior to granting a CE mark a full technical file review will be carried out. The manufacturer must provide all relevant technical documentation in support of the safety and performance claims made for the support surface. Technical documentation is assessed against the essential requirements set out in the EU Directives.

The Notified Body will only issue a CE certificate to show that the support surface meets the requirements, once it has determined a manufacturer has conformed to the relevant assessment criteria. The manufacturer then signs a Declaration of Conformity and applies the CE mark.

Essentially the Notified Body ensures that before medical devices are placed on the market they are safe, effective and any claims made for the device are accurate, realistic and supported by appropriate data.

To differentiate between Class I and Class IIa support surfaces just look at the product CE mark. A Notified Body number after the CE mark clearly indicates a Class IIa device. A CE mark with no number is an unregulated Class I device (see Figure 3).

FIGURE 3.
Labelling differences between Class I devices and Class IIa, IIb and III devices. Figure 3a shows a CE mark from a Class I medical device (e.g. Talley FUSION Response). There is no number after the CE mark therefore this device is NOT audited by a Notified Body. Figure 3b shows a CE mark from a Class IIa medical device (e.g. Talley QUATTRO Plus / Acute). The number after the CE mark is proof that this device is independently audited by a Notified Body.

FIGURE 3a.

FIGURE 3b.

Providing safe, effective, harm free care

A clear and recurring theme across the NHS Outcomes Framework, NICE, CQC and Sign up to Safety is the focus on delivering 'safe, effective, harm free care' to patients.

Without exception 'patient safety' and 'effective care' are board level priorities for all healthcare providers, irrespective of care setting.

Are we honestly 'putting safety first' or 'treating and caring for people in a safe environment and protecting them from avoidable harm' by placing unregulated Class I support surfaces under patients? Who has checked that these mattresses are safe, effective and manufacturers claims are accurate and evidence based?

Conclusion

Powered PAC support surfaces play an essential role in every pressure ulcer prevention and management care bundle. These products should not be low-risk Class I medical devices. Any support surface that is unsafe, ineffective or fails to achieve manufacturers claims of performance and safety, will put patients at an increased risk of pressure related tissue injury!

At a time when budget holders and policy makers are looking to minimise risk, avoid harm and drive reductions in pressure ulcer incidence, it appears a high risk, counter intuitive strategy to rely on unregulated Class I support surfaces to deliver the harm free patient care that everyone 'from board to ward' is striving for.

Surely as an industry and a wound care community we should all be aligned in pushing for tighter regulation and safer support surfaces with quantifiable performance claims? At least by understanding the issues around support surface classification and medical device regulation you can be empowered to drive change and safeguard patients at a local level. This will ensure that your patients receive the safe, effective harm free care they deserve.

Talley Group Limited
Premier Way, Abbey Park Industrial Estate
Romsey, Hampshire, SO51 9DQ England
TEL: +44(0)1794 503500 FAX: +44(0)1794 503555
EMAIL: sales@talleygroup.com
www.talleygroup.com

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