

Bio-Energiser Background

INTRODUCTION

It is recognised that the Xecare Bio-Energiser participates in a market sector where other similar products make various claims that may or not be realised in practice. Consequently, it is reasonable to accept that purchasers and users, of such products, are entitled to establish levels of confidence that any claims, made by a manufacturer, are likely to be reliably and consistently delivered in operation.

To address this requirement, some national governments have introduced schemes of inspections to provide purchasers with a means of verifying or checking up on any claims a manufacturer may make regarding what his product is capable of.

Basically, these governments establish a framework, underpinned by legislation and covering products sold in their countries, that empowers an executive agency of the government to authorise certain independent third parties to go into manufacturers, on behalf of purchasers, to carry out any inspections they feel necessary to satisfy themselves that (a) the manufacturer and his product comply with all requirements in that country [especially safety] and (b) in the case of medical devices, verify any claims the manufacturer has made for his product.

Such schemes are to some extent voluntary for most products in general. But for Medical Devices some countries make it mandatory for such inspections to take place prior to such a device being marketed in their territory.

Essentially, purchasers enjoy regular, independent, authoritative review of manufacturers' claims, carried out, on their behalf, by fully regulated personnel.

THE UK MODEL

The following applies in the UK. Other countries have their own schemes that may vary in some aspects. Of course, for such a scheme to provide the required confidence for purchasers, there has to be high levels of credibility and integrity built in and a robust set of checks and balances.

The UK model demonstrates this as follows:

The UK government empowers the UK Accreditation Service [UKAS].

The United Kingdom Accreditation Service is the sole national accreditation body recognised by government to assess, against internationally agreed standards, organisations that provide certification, testing, inspection and calibration services.

Accreditation by UKAS demonstrates the competence, impartiality and performance capability of these evaluators.

Accredited organisations are authorised to show the UKAS logo adjacent to their own.

Once accredited, an organisation becomes a Registration Body, or Registrar in the USA, or a Certification Body. This means it can carry out the inspections authorised by UKAS, on behalf of customers.

There are several such Bodies operating in the UK, the most recognised, and with the best international reputation, being the British Standards Institution [BSI].

On satisfactory inspection of a manufacturer, BSI issues a Certificate and 'registers' the manufacturer on its records as performing satisfactorily against the Standards or Statutes concerned.

This record is available to purchasers on request, should they wish to verify the inspections.

The manufacturer can, now, and only now, claim to be 'registered' or 'certified' against specific requirements only and promote the fact to its customers by display of relevant logos.

Depending on what the inspections were for, the manufacturer may display one or more different logos as proof of his compliance with specific requirements.

If he has complied with the relevant requirements of European Council Directive 93/42/EEC [also in UK legislation under the Medical Device Regulations] for medical devices, he can display the 'Medical Device CE mark'. This is different from an ordinary CE mark as it has a four digit number identifying to customers the body that carried out the inspections.

If he has only complied with normal electrical safety inspection he can only display the ordinary 'CE Mark' without numbers.

If his management system has been inspected and it complies with the requirements of the Standard for management systems for making medical devices, BS EN ISO 13485:2003, he can display the BSI

registered firm logo together with the UKAS logo. The display must also identify a registration number that allows customers to verify key aspects (see below) of the registration with BSI. Customers can now have high confidence levels regarding the quality and performance of the manufacturer's product.

BIO-ENERGISER CUSTOMER CONSIDERATIONS

In line with what is available to purchasers, as described above, they should do three things:

- Establish whether the device displays a medical device CE mark.

Does the CE mark show it is for a medical device by having a four digit number close to it? If so, is that number the identifier of a body with an international reputation for robust and impartial inspection?

If it does, purchasers can be assured that the device has been reviewed by a credible, independent third party and that characteristics and claims can be accepted with a high degree of confidence and that it conforms to all relevant legislation.

Should they require even further verification, they are at liberty to contact BSI to verify inspections and findings, subject to commercial confidentiality.

- Establish whether the product displays a Registration Body's registered firm logo.

Does the logo have a registration number close to it to allow verification of inspections by the customer and is that logo associated with the UKAS logo?

If so, the customer can be confident that the device is manufactured under a management system conforming to British, European and International standard BS EN ISO 13485:2003, recognised throughout the world as best practice for ensuring consistent reliability and quality.

It also shows the Certification Body to be accredited with UKAS, thus adding credibility to the inspections.

Again, should purchasers require even further verification; they are at liberty to contact BSI to verify inspections and findings, subject to commercial confidentiality.

- Establish the credentials, credibility and background of the inventor/developer of the technology that delivers the claims concerned.

In short, if there is any doubt, purchasers should contact the inspecting body and verify how the manufacturer substantiates any claims

Note: if you are not sure of how 'certification', 'registration' and 'accreditation' fit together in the context of international Standards, there is a fuller explanation at the end of this paper.

CONFORMITY TO MEDICAL DEVICE MARKETING LEGISLATION

The Xecare Bio-Energiser conforms to all the relevant requirements [including functional] of European Council Directive 93/42/EEC relating to Medical Devices and which is incorporated into legislation under the Medical Devices Regulations in the UK and in other countries' national legislation.

The legislation specifies a wide range of essential requirements ranging from safety through medical claims, adverse incidents, user complaints, packaging and instructions. The Directive is available from the EC web site.

This conformity is certified and regularly verified by a credible, independent third party inspector, the British Standards Institution [BSI] which has an internationally recognised reputation for the rigour and diligence of its inspections. Further, this certification establishes the Bio-Energiser as a credible Medical Device distinguishing it from superficially similar devices not so certified, that may or may not be using similar technology but which should limit their claims to un-verified or anecdotal superficial, cosmetic or transient effects.

This means that a user can be confident that any claims made for the BioEnergiser have been reviewed and substantiated through BSI.

Certification entitles Xecare to display a 'Medical Device CE Mark' and users should look for it displayed against the product and in associated literature.

A 'Medical Device CE Mark' is exclusively for medical devices and can be recognised by a four digit number closely associated with the letters 'CE'. Ordinary, non-medical CE marks, as seen on some devices, do not have the number. The four digit code identifies the independent third party carrying out the manufacturer inspections. [e.g. BSI's code is 0086] so users can enquire of the status of any claimed compliance with the inspecting body, subject to commercial confidentiality.

One of the requirements of holding a 'Medical Device CE Mark' is that manufacturers must notify their inspectors of any adverse incidents with their device and that the inspectors are then legally obliged to advise a relevant Notification Authority for the territory concerned. In the UK, the Notification Authority is the Secretary of State acting through the Medical Health Regulatory Authority, an executive agency of the Ministry of Health.

Note: Ordinary 'non-medical CE Marks' do not have a four digit number near the 'CE' and generally only denote that such devices comply with certain electrical safety requirements and has no bearing on effectiveness claims.

Another fundamental and mandatory obligation of holding a 'Medical Device CE Mark' is the identification of clinical data supporting any therapeutic claims made for the device. The following is an extract from the Bio-Energiser technical file summarising the clinical data from which claims are derived.

BioEnergiser Clinical Data Summary Report

Symptoms	Clinician	Dates	No. Patients	Positive Response %	Neutral Response %
Psoriasis	Dr A Dunstan-Fox	Dec2003-Jan 2004	20	80%	20%
Eczema	Dr A Dunstan-Fox	Dec2003-Jan 2004	20	70%	30%
Lymph gland Detox	Dr A Dunstan-Fox	Dec2003-Jan 2004	20	90%	10%
Leg Oedema	Dr M Draper	Sept2004-Jul2005	10	100%	0%
Lymphoedema	Dr M Draper	Sept2004-Mar2005	15	95%	5%
Lymphatic Gland	Dr M Draper	Aug2004-May2005	20	95%	5%
Hyperhydrosis	Dr A Dunstan-Fox	Aug2004-Jul2005	10	90%	10%

Further comments from the clinicians and other testimonials from practitioners and users are available from Xecare on request.

PRODUCT MANUFACTURE.

As a fundamental component of its overall CE Mark certification, Xecare manufactures its BioEnergiser under a management system conforming to British, European and International standard BS EN ISO 13485:2003, recognised throughout the world as best practice for ensuring consistent reliability and quality. The Standard is designed specifically for medical device manufacture.

The Xecare system is verified by a credible, independent third party, the British Standards Institution, a Certification Body, accredited to certify manufacturers against the Standard by UKAS [the UK Accreditation Service] and with an international reputation for rigour and diligence in its inspections of manufacturers.

This means that a user can be confident that any claims made for the BioEnergiser are consistently built into the device right throughout the manufacturing process.

Certification entitles a manufacturer of a device to display the 'BSI Registered Firm' logo in association with the UKAS logo and users should look for it displayed against the product and in associated literature. The number of the registration must be displayed in close association with the logo. The Xecare registration number is MD 93061

If in doubt, purchasers should contact a manufacturer to confirm certain key aspects of the registration: the name of the Certification Body concerned and whether it is accredited to register manufacturers against the Standard for that product, whether the Registration is in force and whether the scope of the registration covers the device concerned. The details can then be confirmed with the Certification Body. The Xecare registration is by BSI, which is accredited to register for this product type by UKAS, and is valid until 2008. The Scope of the registration is taken from the Quality Manual as follows:

The manufacture, distribution and support of neuro-muscular therapy devices.

The following is an extract from the Policy Statement to which Xecare is committed and as shown in the Xecare Quality Manual and as verified by BSI at each inspection:

Policy Statement

Xecare Limited is committed to ensuring the needs and expectations of our customers are the prime driving force behind everything that we do.

It is Xecare Ltd. policy to provide the highest quality of product, fully compliant with the requirements of the European Council Directive 93/42/EEC concerning medical devices and the Medical Devices Regulations of the UK Consumer Protection Act, together with comprehensive, professional support and backup services to our customers.

The Organisation has, therefore, developed and implemented a Management System appropriate to its purposes and complying with the requirements of BS EN ISO 13485:2003. It is committed to maintaining the effectiveness of this System, in all aspects of the business.

The Management System has the full approval of the Director and all objectives and activities within the Organisation are established, controlled and regularly reviewed, by him, for continuing suitability and relevance.

THE INVENTOR

The Xecare group of companies is based on the professional expertise and integrity of its founder and CEO, Dr. Roberto Ciaff who enjoys an influential reputation in the field of Neurology.

Based on a career starting in general medicine and moving onto Forensic Medicine, Dr Ciaff holds a scientific position and a fellowship with the **Royal Society of Medicine**. He has worked in research & development and held senior positions with fortune 200 companies such as Johnson & Johnson and Bayer.

Dr. Ciaff has spent over 20 years developing his Sigma'Q' - 'Q' Phase - Qenergy - Micro-Photoluminescence'Q' and Quaver technologies for practical application in a range of diagnostic and therapeutic fields.

His main driving force is his passionate belief that the benefits of his discoveries should be made available to those who can benefit whenever and wherever they are needed. Hence the introduction of the BioEnergisier for self administered, home use.

He continues to develop and design revolutionary technologies for various medical, healthcare, equine and cosmetic applications.

CONTACT INFORMATION

From within the UK:

The European Council Directive can be downloaded from: europa.eu.int/comm/enterprise/newapproach/standardization/harmstds/reflist/meddevic.html

BSI can be accessed through their comprehensive web site: <http://www.bsi-global.com/>

The ISO organisation can be accessed through their web site: <http://isotc.iso.org/>

UKAS can be accessed through their web site: www.ukas.com

Relevant Notification Authorities for European markets can be accessed from http://europa.eu.int/comm/enterprise/medical_devices/ca/ca_vig.htm

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The following is an edited extract from the ISO web site:

Certification, Registration and Accreditation

The ISO 9000 [management systems], ISO 13485 [management systems -Medical Devices] and ISO 14000 [management systems –environment] families of international Standards each contain a single standard to which manufacturers can be “certified”. "Certification", "Registration" and "Accreditation" are three words that will certainly crop up whenever purchasers seek to verify claims made by manufacturers. Just what exactly do they mean? Let's first take the first two.

According to the standardised definitions, ‘certification’ and ‘registration’ are not quite the same things. In the context of ISO 9001:2000 or ISO 13485:2003 or ISO 14001:2004, "**certification**" refers to the issuing of written assurance (the certificate) by an independent, external body that has audited an organisation's management system and verified that it conforms to the requirements specified in the relevant Standard. "**Registration**" means that the auditing body then records the ‘certification’ in its client register.

The organization's management system has therefore been both certified and registered in the context of the above Standards. For practical purposes, the difference between the two terms is not significant and both are acceptable for general use.

"Certification" seems to be the term most widely used worldwide, although “registration” (from which "registrar" as an alternative to registration / certification body) is often preferred in North America, and the two are also used interchangeably.

Using "accreditation" as an interchangeable alternative for certification or registration is a mistake, because it means something different. In the context of the subject Standards, “accreditation” refers to the formal recognition, by an authorised body - an Accreditation Body, that a Certification Body is competent to carry out ISO 9001:2000, ISO 13485:2003 or ISO 14001:2004 certification in specified business sectors. In simple terms, accreditation is like certification of the certification body. Certificates issued by accredited certification bodies - and known as "**accredited certificates**" - **may be perceived on the market as having increased credibility**.

Therefore, to increase market credibility, it is okay to state that a manufacturing organisation's management system has been "certified" or "registered" (if, indeed, it has!), but inaccurate to state that it has been "accredited" (unless the organisation is a certification/registration body).