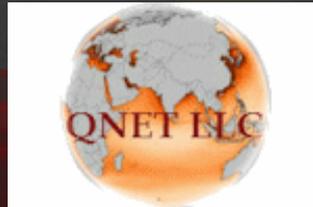


CE Marking Medical Devices



Issues to Consider Before Starting Compliance

CE Marking Medical Devices in accordance with Medical Device Directive 93/42/EEC

- Is it a Medical Device or an Accessory?
- Is it Personal Protective Equipment?
- Who is the manufacturer?
- How to determine Risk Classification
- Meaning of the words Shall and Should
- About Risk Class 1 devices
- Does the RoHS Directive apply?



Definition of a device is:

‘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:



Definition of a device is:

- diagnosis, prevention, monitoring, treatment or alleviation of disease,
- diagnosis, 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;



Definition of an Accessory:

The definition of an “accessory” requires that the accessory is specifically intended by the manufacturer of the accessory to be used together with a device. The intended use of the accessory must be such as to enable a device to be used in accordance with its intended use. Therefore a product can only become an accessory to a medical device if the manufacturer of such a product establishes an intended use in conjunction with one or several medical devices.



Definition of Personal Protective Equipment

PPE shall mean any device or appliance designed to be worn or held by an individual for protection against, one or more health and safety hazards.

Intended Use Examples: Protection against radiation exposure.



NO-BRAINER®

REGULATORY VOYAGE TO SUCCESS

By: Mr. John Cadwalader – Founder

Worldwide Innovations and Technologies, Inc.

**A medical device manufacturer of lead free
radiation shielding devices.**





YEAR 2011

- New product design of RADPAD[®] **No-Brainer**[®]
- Sold in the U.S. and non-EU countries for 5+ years.
- RADPAD distributors in EU want to sell the No Brainer[®]
- EU regulations consider us a manufacturer of Personal Protective Equipment (PPE)
- Need to comply with Personal Protective Equipment Directive
- Luckily our medical device Notified Body can also certify PPE
- Start PPE compliance efforts



YEAR 2012

- Notified Body agrees to work with Worldwide on PPE
- PPE Notified Body admits lack of experience dealing with **NO BRAINER**[®] unless we can identify a testing standard
- Unable to identify EU, US or other National Standard
- We contacted 36 alternative PPE Notified Bodies
- All require that we identify a testing standard and since none has been found they are unable to certify



YEAR 2013

- Contact US Department of Commerce
- Meeting with Assistant Secretary of Commerce
- **NO-BRAINER**[®] case is referred to US Mission to the EU for handling
- **NO-BRAINER**[®] case becomes example of Trade Barrier on Transatlantic Trade and Investment Partnership agreement negotiations (TTIP)
- US Mission to the EU delegates meeting in Minneapolis which results in identifying a US Standard!!! **PIVOTAL!!!**
- **NO-BRAINER**[®] is tested against US Standard and passes
- Contact Notified Body with good news!!! Let's move!
- Notified Body declines! Claims that even with Standard they lack internal expertise! WASTED 2 YEARS!
- Start search for alternative Notified Body



YEAR 2014

- ▶ Sign agreement with new Notified Body
- ▶ August: Technical file review and on-site audit completed

CE Certificates are received



SUCCESS

September: **RADPAD NO-BRAINER**® introduced at CIRSE medical conference in Scotland

Result: 100 inquiries from 20 countries and 8 EU

Distributors start selling **NO-BRAINER**®

We increase production!



Thank You



Who is the medical device manufacturer?

‘Manufacturer’ means the natural or legal person with responsibility for the design, manufacture, packaging and labelling of a device before it is placed on the market under his own name, regardless of whether these operations are carried out by that person himself or on his behalf by a third party.

In plain English: If your company places its name on the device your company is considered the manufacturer.

Number 1 problem: for marketing companies, joint branding agreements, etc.

Remember: CE marks are not transferable!



How to determine Risk Classification

Device Risk classifications must be justified based on risk rules.

Classification determines compliance process:

Self-certification – Risk Class 1

Notified Body Certification: Risk Class I plus measuring function

Risk Class I plus sterilization

Risk Class IIa

Risk Class IIb

Risk Class III

Supporting documents: Medical Device Directive, MedDev 2.4/1 Rev 9,
Manual on borderline Classification Version 1.15.



Meaning of the words shall and should

Warning , when reading these documents

The words 'shall' and 'should', in plain English, means **MUST**



About Risk Class I Devices

Risk Class I Compliance Steps Are:

- 1) Compilation of technical file containing:
 - Declaration of Conformity
 - Classification justification
 - General information about device, suppliers, EU countries, etc.
 - Labels: Translation and EU symbols, etc.
 - Instructions for Use: Translations and EU symbols
 - Risk Assessment in accordance with ISO 14971
 - Essential Requirements: Biocompatibility, flammability information, etc.
 - Procedures for: Translations, vigilance, post marketing review, etc.
 - Evaluation of clinical data
- 2) EU Authorized Representative – EU Registration
- 3) RoHS Directive technical file electrical/electronic devices



Does the RoHS Directive apply?

RoHS Directive 2011/65/EU (RoHS2) covers:

Six hazardous substances and maximum concentration values tolerated by weight in electronic and electrical medical devices.

1. Lead (Pb) <0.1%>
2. Cadmium (Cd) <0.01%>
3. Mercury (Hg) <0.1%>
4. Hexavalent Chromium (Cr (VI)) <0.1%>
5. Polybrominated biphenyls (PBBs) <0.1%>
6. Polybrominated diphenyl ethers (PBDEs) <0.1%>

Effective 22 July 2014



RoHS2 Compliance

After 22 July 2014 compliance with both:
Medical Device Directive 93/42/EEC
PLUS
RoHS Directive 2011/65/EU

Is required **BEFORE** you can CE Mark an electrical/electronic medical device.

Thank You