How to get a CE Mark for a Rebreather

http://www.rebreatherworld.com/showthread.php?10345-How-to-get-a-CE-Mark-for-a-Rebreather

CE marking for Rebreathers and PPO2 Monitors

Each country in Europe has ratified an EC Directive on Personal Protection Equipment (PPE) [Anmerkung: deutsch "persönliche Sicherheitsausrüstung / PSA"]. This requires that any equipment that falls within the scope of any European Standard that is designated a PPE Type C standard [Anmerkung: PSA Kategorie III] be certified by an accredited and competent PPE Notified Body. When it is properly certified it must carry a CE mark, but not until then.

Any person or company that is importing, manufacturing, selling or using equipment for work [Anmerkung: dies stimmt nicht; die Direktive gilt auch für das sog. Recreational Diving!] that falls within a Type C standard, requires a valid CE marking on the equipment. If it does not have a valid CE marking, then they are breaking the laws or regulations in their country, and the enforcement body in that country can ban the import, obtain court injunctions to stop manufacture or sale and seize the goods. If there are accidents from use of such equipment, it may become a criminal liability for the directors of the company involved.

Clearly, no responsible company would want to be in this position, so lack of a valid CE certification for the equipment amounts a complete blacklisting of the equipment in Europe.

1. The Law and Regulations

The PPE Directive is ratified by each country in Europe. Many not in Europe have complementary requirements.

In the UK for example, the Directive is ratified as *Personal Protective Equipment (EC Directive) Regulations S.I. 1992/3139, implementing Council Directive 89/686/EEC as amended by the Personal Protective Equipment (EC Directive) (Amendment) Regulations S.I. 1993/3074 implementing Council Directive 93/95/EEC and the Personal Protective Equipment (EC Directive) (Amendment) Regulations 1994 S.I. 1994/2326 implementing Council Directive 93/68/EEC as it relates to PPE.* These regulations are issued by the UK Department of Trade and Industry (DTI).

As regards what is included in PPE and what is not, contacting a Notified Body can lead to confusion, as the individual who answers the enquiry may not be qualified to do so. The only safe route is to check the Official Journal of the European Commission web site at EUROPA - European Commission - Homepage, which contains a list of the Type C standards that are harmonized under the European Directives. The page for all the standards, which give presumption of conformity to the PPE Directive, is Enterprise - New Approach - Harmonized standards for personal protective equipment. On that list is CEN EN 14143:2003 Respiratory equipment - Self-contained re-breathing diving apparatus 6.10.2005. This is adopted in the UK as BS EN14143:2003.

EN14143:2003 covers all rebreathers and also all PPO2 monitors for use with a rebreather that is imported, manufactured, sold or used in work in Europe.

As EN14143:2003 is on the Directive's PPE C list, certification of the equipment by an accredited PPE Notified Body is mandatory. It is not permitted to self-certify, or for anyone

else to certify other than a PPE accredited Notified Body whose accreditation includes "respiratory equipment including dive equipment".

2. Finding a Competent Notified Body

The word “competent” here means legally authorized. It does not refer to their ability.

To find an accredited Notified Body, a check was made of the accreditation of all 1900 Notified bodies listed on the site EUROPA - European Commission - Enterprise - Single market - NANDO

This identified just TUV and SGS Yardley as being accredited to audit equipment to EN14143:2003, with BSI and Isoquar still examining whether they are accredited and competent to carry out such an audit. Inspec International indicated they may be accredited but an audit would take one year to carry out (i.e. the five days needed to perform the audit and report, would start a year from the date they were contracted).

To ensure no other companies had been missed, the UK DTI was contacted. The contact point for anyone who is looking for updates is:

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Personal Protective Equipment (PPE)
http://www.dti.gov.uk/innovation/str...ect/index.html
Department of Trade and Industry
Room 280
151 Buckingham Palace Road
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mailto:Ana.Nicola@dti.gsi.gov.uk

Ana Nicola kindly sent the direct link to the UK Notified Body list, as the UKAS and DTI sites had missing links to that document.
http://www.dti.gov.uk/files/file1190...dload=05%2F403

All companies on that list were contacted and this confirmed that they were PPE Notified Bodies but none other than those already listed were accredited to carry out an audit for EN14143. Moreover, none of the PPE Notified Bodies in Europe is accredited to certify any equipment to EN61508, nor carry out any EN61508 audit. EN14143:2003 requires compliance with EN61508.

The only accredited auditor for EN61508 in Europe is SIRA Certification. This means that SIRA must carry out an audit and certify either the equipment under test, or the process used to design the equipment and control its life cycle, to either SIL 3 for very low volume equipment, or SIL 4 for mass produced equipment.

If an EN14143:2003 certificate is issued without an EN61508 certificate having been issued by SIRA, then the EN14143:2003 certification is incompetent. Any such certificate in issue will not stand up in law.

It is my opinion that when the certification process is complete, the company manufacturing or controlling the manufacture of the equipment will have at least four certificates:

1. **EN61508:2004 Certification** for either the equipment itself or the process used to design and manufacture the equipment, to SIL 3 if the equipment is low volume, and SIL 4 if high volume. The SIL rating depends on how many people any design fault can kill, which depends on its expected volume of sales and usage. At present, this certificate can only be issued by SIRA Certification.
2. **EMC Compliance certificate** issued to Electromagnetic Compatibility Directive 89/336/EEC as Amended by Directive 92/31/EEC, by a Notified Body or the full data included in the Technical File for the equipment. The number of the standard adopting this varies from country to country.
3. **EN14143:2003 Type Approval Certificate**, a Type 10 certificate covering the design. This is issued by one out of TUV, SGS Yardley, BSI, or possibly Isoquar or Inspec. The EN61508 compliance certificate must exist first, otherwise the EN14143:2003 certificate is incompetent.
4. **EN14143:2003 Type 11 Approval Certificate** covering the manufacturing plant making the equipment.

Other certificates may be required if the equipment includes custom regulators (EN250) or other special features.

3. Underlying Requirements

To meet EN61508 or EN14143, the company manufacturing that manufactures the goods will have to be registered to ISO 9001.

To meet EN61508, the Project Leader responsible for the team that designed the equipment must be a Fellow of the Institute of Electrical Engineers, FIEE, or an equivalent in another country, i.e. an FIET, though the FIEE requirement is in fact more onerous than to become a FIET.

The company carrying out the design should have extensive quality procedures dealing with the design of safety critical products, to meet EN61508.

These requirements mean that an individual, who designs a rebreather, cannot just put if forward with some test results and a statement that they think it is safe. It requires a formal safety procedure to be followed, where the individuals doing the work are trained and competent in the technical sense, or at least certified with evidence of competency being required to obtain the certification.

4. Is this really needed or just red tape?

EN14143:2003 is a standard that a panel of very experienced engineers, with extensive diving experience, have written as a *minimum safety standard* that should be achieved.

For EN61508 the ALARP principle is applied. Other than that, part of meeting EN61508 is proving that when the equipment needs to be used, it fails to work less than once in 100,000 hours. If equipment met that, it would save users money, time and many lost dives. The equipment is not permitted to fail in a dangerous state more often than once in 100 million

hours (SIL 3) or a billion hours (SIL 4).

It is my opinion that deaths have occurred on rebreathers just because companies have ignored these regulations. If anyone suggests these safety requirements are excessive or "over the top", then they both differ with the experts on the CEN-SC/ panel and have not seen enough of the results of failures in safety. It is highly recommended that before anyone starts down the path of designing any rebreather, they read the account written by a widow in a dive accident caused by equipment failing to meet EN61508, available on http://www.rebreatherworld.com/attac...0&d=1160677633

If companies meet these safety requirements, it would benefit their sales, their customers and the whole industry, as it would build up trust in their product, and the procedure to ensure safety would lead to safer products.

Credits:
Thanks to:

- To Brent Hudson for correcting information on a key point.
- To SIRA Certification and each of the Notified Bodies listed here.