Legislation related to CE type approval of rebreathers, judgement allowed by the Notified Body.

Law: directive 89/686/EEC

The Personal Protective Equipment (PPE) Directive (89/686/EEC) was adopted on 21 December 1989 and became Community Law on 1st July 1992.

Ref: http://www.county-safety-services.com/_docs/89-686-EEC.pdf (1) (simplified version)

The full text of 89/686/EEC: http://eur-lex.europa.eu/smartapi/cgi/sga_doc?smartapi!celexapi!prod!CELEXnumdoc&lg=en&numdoc=31989L0686&model=guichett (2)

The directive provides classification of PPE's from very simple to very complex PPE's, from category I to category III

Rebreathers fall under category III (see 1)

How can CE type approval be carried out for category III: (see 1 and in detail 2)

G 3.1.3 Category III

To attach the CE Marking, the Manufacturer must, according to the Directive, carry out similar procedures (a) to (e) as for Category II, with the additional procedure for checking of PPE Manufacture (Article 11A or 11B).

In Article 11A - "EC quality control system for the final product II - the Manufacturer requests a Notified Body to ensure that the P.P.E. conforms with the EC Type Examination Certificate by checking random production samples at least once a year. The Notified Body then issues the manufacturer with a test report.

In Article 11B - "System for ensuring EC quality of production by means of monitoring" - the manufacturer has his quality control system approved by a Notified Body (A system conforming to EN 29003 would be suitable).

CE Marking may be authorised, where article 11A is used, using Modules B and C and where Article 11B is used, using Modules B and E, according to Community Assessment Procedures in Community Legislation.

So it must include all procedures of category II, and add article 11a or 11b of the directive.

G 3.1.2 Category II
In this category to attach the CE Marking the Manufacturer must, according to the Directive, : -
(a) Ensure either (i) the product complies with harmonised European Standards or (ii) the product complies with verified technical specifications.
(b) Assemble technical documentation for submission to the Notified Body (Article 8 and Annex (iii)).
(c) Make application for EC Type examination to the Notified Body (Article 10).
If satisfied, the Notified Body draws up an EC Type Examination Certificate and notifies the manufacturer to this effect.
The Manufacturer then : -
(d) Draws up a Declaration of Production Conformity (Article 12 and Annex vi).
(e) Affixes CE marking (article 13 and Annex iv).
CE Marking may be authorised via Module B according to Conformity Assessment Procedures in Community Legislation.

In the directive, the law, it is clearly included that there is the need of a Notified Body, (G 3.1.2 (b) and (c)), and that the Notified Body is allowed to make a judgement, to choose between the harmonised standard, or verified technical specifications.

See above category II G 3.1.2 (a):

*(a) Ensure either (i) the product complies with harmonised European Standards **or** (ii) the product complies with verified technical specifications.*

The directive also specifically points out, that there is no obligation to use the harmonised standard, even when available:

See in detail: (2) article 10.4.a and 10.4.b of the directive 89/868/EEC

> *4. The inspection body of which notification has been given shall conduct the EC type-examination in accordance with the undermentioned procedures:*
>
> *(a) Examination of the manufacturer's technical file*
>
> *- It shall examine the manufacturer's technical file to establish its suitability with respect to the harmonized standards referred to in Article 5.*
>
> ***- Where a manufacturer has not applied, or has only partly applied, the harmonized standards or where there are no such standards, the body of which notification has been given must check the suitability of the technical specifications used by the manufacturer with respect to the basic requirements before examining the manufacturer's technical file to establish its suitability with respect to these technical specifications.***
>
> *(b) Examination of the model*
>
> *- When examining the model, the inspection body shall verify that it has been produced in accordance with the manufacturer's technical file and can be used in complete safety for its intended purpose.*
>
> *- It shall conduct the necessary examinations and tests to establish the conformity of the model with the harmonized standards.*
>
> ***- Where a manufacturer has not applied or has only partly applied the harmonized standards or where there are no such standards the body of which notification has been given shall conduct the necessary examinations and tests to establish the conformity of the model with the technical specifications used by the manufacturer, subject to their being suitable with respect to these basic requirements.***

Why would the law, the directive allow to NOT use a harmonised standard, and leave judgement to the notified body?

Multiple reasons:

- **there can be errors in the standard, so that makes it impossible to comply with**
- **the standard can be outdated: for PPE's where there is fast technological evolution going on, the standards can not be adopted as fast as the technology on the market changes.**

Typical for rebreathers:

- **The technology of rebreathers is changing constantly and improving, new developments come on the market.**
- **Current rebreather technology is less then 15 years old**

- **The standard for rebreathers, EN14143, is written almost 10 years ago, and does not include the new developments on the market (for example manually operated rebreathers)**

Conclusion:

At this moment, all CE type approvals of rebreathers are only partly complying with the harmonised standard, (using the standard but excluding some articles of the standard), or complying with technical specifications, but both approved by the Notified Body.

See also:

*** to find the current list of Notified Bodies**

http://ec.europa.eu/enterprise/sectors/mechanical/personal-protective-equipment/