

Docket Management Branch
Division of Management Systems and Policy
Office of Human Resources and Management Services
Food and Drug Administration
Room 1061, HFA-305
5630 Fishers Lane
MD 20582 Rockville
USA

Basel, Switzerland, 8. April 2002

Public comment concerning the guidance document number 1335

Ref.: Class II Special Controls Guidance Document: Cutaneous Carbon Dioxide (PcCO₂) and Oxygen (PcO₂) Monitors; Draft Guidance for Industry and FDA

Gentlemen,

We would like to comment about the above mentioned Class II Special Controls Guidance Document that has been released on February 12, 2002.

Our group is active in developing cutaneous blood gas equipment in Basel, Switzerland, since 1969, earlier as a department of Hoffmann-La Roche AG, then as part of the company Kontron Instruments Ltd, and since 1999 as an independant company Linde Medical Sensors AG. Our cutaneous sensors and monitors are distributed worldwide and are CE marked and FDA approved (MicroGas 7650 and PO₂/PCO₂ Combi sensor type 82).

We have read with interest your guidance proposal but instead to comment the proposal in details we would rather have the following general comment: when developing cutaneous blood gas equipment we are presently following the International Standards IEC 60601-1, covering the general requirements for medical equipment and IEC 60601-2-23, second edition 1999-12, which covers also the scope of IEC 60601-3-1, 1996-07. These standards cover essentially the same requirements related to the cutaneous parameters and equipment as your proposed guidance and are more actual than the IEC 601-2-23, 1993-09 and ASTM F 984-86 (reapproved in 1992) that you mentioned in your guidance.

We therefore wonder if you could not consider to use the same standards (IEC 60601-2-23, second edition 1999-12 and IEC 60601-1) for your guidance, or just refer to these standards, and if not we would be very interested to know your rationale.

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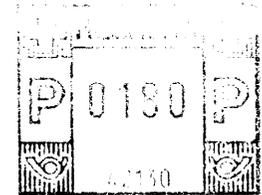
Thank you for your understanding, I remain

A handwritten signature in black ink, appearing to read 'P. Eberhard', with a long horizontal stroke extending to the right.

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A Prioritaire



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