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Supports the request for exemption No. 2013-1 to the annex IV of Directive 2011/65/EU

Dear Carl-Otto Gensch

Radiometer Medical ApS (Radiometer) supports the request for exemption No. 2013-1 to the annex IV of Directive 2011/65/EU. Radiometer uses lead as a thermal stabilizer in Polyvinyl Chloride (PVC) in a similar application.

In our application, the PVC material is used for containing an electrochemical sensor and a sensor membrane for measurement of e.g. calcium (Ca⁺⁺) and potassium (K⁺) in human blood samples.

Although the chemical properties of the material used by Radiometer seems to be of similar type as used by the applicant for the exemption, the physical environment is a little different, and therefore Radiometer propose a slightly changed wording for the exemption so the exemption will focus on the chemical properties of the materials and not on the surrounding materials.

Radiometer proposes this wording in the exemption:

“Lead as thermal stabilizer in Polyvinyl Chloride (PVC) used as base material in amperometric, potentiometric and conductometric electrochemical sensors.”

Radiometer has tested an alternative stabilizer, which we already use in other sensor types, but this resulted in poor performance of the measuring devices when measuring K⁺ and Ca⁺⁺ ions, as can be seen from the attachment. The alternative material shows both a lower sensitivity and a number of unstable measurements during the 90 days lifetime test of the sensor. This will result in poor and degrading performance, meaning significantly inferior clinical performance specifications.

The PVC base material is also required to be compatible with the rest of the sensor unit; otherwise this cannot be assembled with the sensor membrane.

All in all this means it will not be possible to substitute the PVC material without a major redesign, clinical re-validation and re-approval of the equipment by the authorities.

The test of alternative stabilizer materials is time consuming; each material needs to be tested for at least 90 days, and also a shelf stability test of 26 months has to be passed. We expect it will take at least 3-5 years to substitute lead as the stabilizer for the K⁺ and Ca⁺⁺ sensors.

To summarize, Radiometer supports the exemption request 2013-1 with the new wording as suggested above.

Best Regards,
Radiometer Medical ApS

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