

[REDACTED]

To whom it may concern
Öko-Institute e.V.
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Germany

Datum: 03.12.2017 [REDACTED]

Support for the request for renewal to the Annex IV to Directive 2011/65/EU

Sehr geehrte Damen und Herren,

I hereby strongly support the request for renewal for Annex IV Ex. No. 41. of Directive 2011/65/EU in response to Consultation Questionnaire question 5e.

Our hospital and laboratory vitally depends on results from blood gas analyzers such as the Instrumentation Laboratory GEM Premier products. Currently we have 16 GEM 4000 and GEM 5000 analyzers in use at our hospital. Per year we report over 175.000 patient results. Our patient population would be seriously and adversely impacted if these manufacturers were blocked from supplying these instruments.

The current product technology is well known proven and has the necessary level of reliability. Reliability in performance of these analyzers is vital and absolutely non-negotiable.

We would be compromised in providing a good quality of healthcare to our citizens without blood gas results from these analyzers. Our physicians require this data for insights into the best treatment plan, or management of diseases to assure a good quality of life.

Therefore, our 700 bed hospital and trauma center would be critically impaired in maintaining the effectiveness of our patient care, as well as the safety of patients in receiving the proper treatment if our access to these instruments were jeopardized. This matter is so extremely urgent to me that I am even writing to you while I am on a vacation trip in South-East Asia.

Thank you very much for considering our feedback in support of the renewal request for Annex IV Ex. No. 41.

Please feel free to contact me directly in case of any further questions.

Kindest regards

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