To: Oeko-Institut/Fraunhofer IZM
Öko-Institut rohs.exemptions@oeko.de

Date: October 15, 2015

From: Kevin Cooper
Senior Principal Quality Engineer, ASQ, CQE, CQA
Baxter Healthcare Corporation
Medical Products Division
email kevin_cooper@baxter.com
USA phone 224-270-5151

1. Regarding: Request for renewal of Exemption 4(a) "Mercury in other low pressure discharge lamps (per lamp)

Baxter Healthcare request the renewal of Exemption No. 4a of Annex II with the same wording formulation (same as NARVA proposal).

Baxter Healthcare currently distributes the product code 5H52101 "Vivia Water Device" with CE Mark certification review from TUV SUD Product Service GmbH.

Product Description:

The **Vivia** Water Device is designed to provide chemically and microbiologically purified water for use in hemodialysis treatments delivered exclusively by the **Vivia** Hemodialysis System, and to supply the additional water requirements of the **Vivia** Treatment Device. The **Vivia** Water Device uses standard tap water that meets the requirements of the United States Environmental Protection Agency Safe Drinking Water Act, European Union Directive, or Guidelines for Canadian Drinking Water Quality as a feed water source. The **Vivia** Water Device generates product water that meets or exceeds the chemical requirements of the European Pharmacopoeia (EU Pharmacopeia monograph 1167, Water for Diluting Concentrated Haemodialysis Solutions), ANSI/AMMI/ISO 26722:2009 (Water Treatment Equipment for Hemodialysis Applications and Related Therapies), ANSI/AMMI/ISO 13959:2009 (Water for hemodialysis and related therapies), and ANSI/AMMI/ISO 23500:2011 (Guidance for the preparation and quality management of fluids for hemodialysis and related therapies), and that meets or exceeds the bacterial requirement of the European Pharmacopoeia Best Practice Guidelines (EBPG) for "Ultrapure Water". However, while the **Vivia** Water Device design is capable of producing ultrapure water, required customer device water and dialysate sampling, testing, and related purity claims shall be based on established limits from the applicable standards to avoid collection and test method complexities and excessive costs.

The **Vivia** Water Device interfaces with the **Vivia** Treatment Device to allow the two devices to communicate with each other. The Treatment Device directs the **Vivia** Water Device when to start and stop. The **Vivia** Water Device informs the **Vivia** Treatment Device of its status, such as the filter life, current state, or alarm and alert signals. This information is then provided to the user on the touch screen of the **Vivia** Treatment Device.

Baxter's sources this product from Merck Millipore
39 Route Industrielle de la Hardt
67120 Molsheim, France

The product utilizes a UV lamp in accordance with ISO 26722:2014 as critical state of the art medical device means of control bacterial proliferation in the preparation and distribution of water for haemodialysis.

Standard BS ISO 26722:2014 / ISO 26722:2014(E) “Water treatment equipment for haemodialysis applications and related therapies”, under section 4.2 “Water treatment equipment requirements”/4.2.1 “General”/4.2.13 “Storage and distribution of dialysis water”, includes 4.2.13.2 Ultraviolet irradiators as a means to control bacterial proliferation in dialysis water storage and distribution systems. The standard states that “When used to control bacterial proliferation in dialysis water storage and distribution systems, UV irradiation devices shall emit light at a wavelength of 254 nm and provide a dose of radiant energy of 30 mW sec/cm^2. If the irradiator includes a calibrated ultraviolet intensity meter, the minimum dose of radiant energy should be at least 16 mW sec/cm^2. …”

Currently UV lamps containing a small amount of mercury are the only available technology that are commercially available which can provide ultraviolet irradiation at the wavelength and intensity required by this standard. This exemption will continue to be needed to provide haemodialysis patients safe and effective treatment for the foreseeable future. I don’t know of a suitable commercial alternative that will be available in the next ten years.

Multiple haemodialysis water systems in hospitals and clinics, from multiple manufactures, utilize UV lamps containing mercury to control bacterial proliferation in accordance with the means allowed in ISO 26722 standard.

Regards,
Kevin Cooper