Carl-Otto Gensch
Öko Institute
By email: rohs.exemptions@oeko.de

Brussels, 10 March 2014

Re: Consultation on EEE newly in scope of RoHS

Dear Mr Gensch,

Eucomed and EDMA, the industry associations representing the medical devices (MD) and in vitro diagnostic (IVD) medical devices sectors respectively, welcome the opportunity to provide further input with regards to the need for secondary market operations for medical technologies as well as related products which may fall under Category 11 of Directive 2011/65/EU ("RoHS2").

EDMA and Eucomed represent manufacturers of CE-marked IVDs and MDs, i.e. those products which fall under Category 8 of RoHS2. Our products are defined by their use for human medical purposes and as such we do not represent products for veterinary or forensic use. However we assume that there are many similar products in the medical veterinary and forensic fields as well as 'medical devices' which are intended for research or training purposes only: these products might fall under Category 11 of RoHS2.

Out of the five proposed scenarios, by preference we support Scenario C (to delete Art. 2.2 and amend Art 4.3 with Category 11 date) as well as its complementary Scenario E (addition of a spare parts provision for Category 11 in Art. 4.4) as these would support the market in refurbished products equally for categories 8, 9 and 11. By secondary preference we would however still support Scenario B (Art. 2.2 wording amended to exclude categories 8 and 9) which would allow secondary market operations for CE-marked MDs and IVDs. Our responses in the enclosed table should be seen in this context.

As sections 3-5 of your questionnaire are product-specific and designed for Category 11 (rather than categories 8 and 9) our enclosed input addresses the scenarios laid out under Section 6 only.

We trust that your investigation will take into account the considerable analyses already performed by the ERA[1], BioIS[2] and further re-summarised and analysed by the UK Department for Business, Innovation & Skills[3] as noted on your consultation website. Rather than repeat the ground already well covered by these comprehensive analyses, our responses in the enclosed table will be brief in

[1] Review of Directive 2002/95/EC (RoHS) Categories 8 and 9", Dr Paul Goodman, ERA Technology (2006)
[2] Measures to be implemented and additional impact assessment with regard to scope changes, pursuant to the new RoHS Directive, BioIS (2012)
[3] Final Impact Assessment for Recast of the Restriction of Hazardous Substances (RoHS) Directive, BIS (2012)

summarising some of the key points. Should the Öko Institute need further detail on any points however you are warmly welcomed to return to EDMA and Eucomed for this information.

EDMA and Eucomed kindly ask that the Öko Institute take the economic, legal and environmental impact of Article 2.2 on the MD and IVD industries as well as on our consumers –hospitals, laboratories and ultimately patients – into account in your final recommendations to the European Commission. We further support a compliance deadline and provision for secondary market operations for Category 11 products, some of which may include products similar to those under Category 8.

Yours Truly,

Petra Zoellner
Regulatory Affairs Manager
EDMA

Merlin Rietschel
Manager Regulations and Industrial Policy
Eucomed