# Independent Assurance Report

Ecodesign Steering Committee Secretariat ("COCIR") Brussels

Limited assurance engagement on the preparation process of selected data of the Status Report of the SRI for Medical Imaging Equipment under the Ecodesign Directive (the "SRI Status Report") for the year 2014

Engagement: 0.0760424.001



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#### INDEPENDENT ASSURANCE REPORT

To the Ecodesign Steering Committee Secretariat ("COCIR") of the Self-Regulatory Initiative ("SRI") for Medical Imaging Equipment under the Ecodesign Directive, Brussels

We have been engaged to perform a limited assurance engagement on the preparation process of selected data of the Status Report of the SRI for Medical Imaging Equipment under the Ecodesign Directive (the "SRI Status Report") for the year 2014.

# Responsibility for SRI Status Report 2014

The Ecodesign Steering Committee of the SRI is responsible for the preparation of the SRI Status Report in accordance with the six step methodology as stated in the SRI V1 (for ultrasound imaging equipment) and SRI V3 (for MRI, CT and future modalities):

- Step 1: Gather baseline data
- Step 2: Prioritization and selection of next modality
- Step 3: Identification of significant environmental aspect(s) for the selected modality
- Step 4: Derive environmental targets and objectives for the selected modality
- Step 5: Implementation into company processes
- · Step 6: Monitoring and reporting

This responsibility includes the selection and application of appropriate methods to prepare the annual SRI Status Report and the use of assumptions and estimates for individual SRI disclosures which are reasonable in the circumstances. Furthermore, the responsibility includes designing, implementing and maintaining systems and processes relevant for the preparation of the SRI Status Report.

#### Practitioner's Responsibility

Our responsibility is to express a conclusion based on our work performed as to whether any matters have come to our attention that cause us to believe that the preparation process for the data in the SRI Status Report 2014 marked with the logo  $\checkmark$  has not been, in all material respects, in accordance with the above mentioned SRI six step methodology. We also have been engaged to make recommendations for the further development of the reporting of the SRI based on the results of our assurance engagement.

Within the scope of our engagement we did not perform any procedures on the data that have been submitted by the member companies to the Ecodesign Steering Committee Secretariat (COCIR). Thus, we provide limited assurance on the preparation process of the SRI Status Report 2014 by COCIR, but not on the respective data.

We conducted our work in accordance with the International Standard on Assurance Engagements (ISAE) 3000. This standard requires that we comply with ethical requirements and plan and perform the assurance engagement under consideration of materiality to express our conclusion with limited assurance.

In a limited assurance engagement the evidence-gathering procedures are more limited than in a reasonable assurance engagement, and therefore less assurance is obtained than in a reasonable assurance engagement.

The procedures selected depend on the practitioner's judgement. Within the scope of our work we performed amongst others the following procedures:

- Inquiries of personnel at the Ecodesign Steering Committee Secretariat (COCIR) responsible for the preparation of the SRI Status Report regarding the process to prepare the Report and the underlying internal control system;
- Inspection and sample testing of the systems and process documentation for collection, analysis and aggregation of the selected data;
- Recalculation of the aggregation and KPIs calculation for selected data;
- Analytical procedures on selected data;
- Inspection of documents regarding the description of the SRI six step methodology (SRI V3) and its application to MRI as detailed in 'Magnetic resonance Equipment (MRI) Study on the potential for environmental improvement by the aspect of energy efficiency' and 'Magnetic Resonance Measurement of energy consumption'.

#### Conclusion

Based on our limited assurance engagement, nothing has come to our attention that causes us to believe that the preparation process for the data in the SRI Status Report 2014 marked with the logo ✓ has not been, in all material respects, in accordance with the above mentioned SRI six step methodology.

### Emphasis of Matter - Recommendations

Without qualifying our conclusion, we make the following recommendations for the further development of the reporting of the Self-Regulatory Initiative for Medical Imaging Equipment under the Ecodesign Directive:

- Develop a policy to require the SRI members to submit assurance certificates for annual sales data and data on the environmental aspects in scope for each modality
- Improve effectiveness and documentation of controls

## General Terms of Engagement

We issue this report on the basis of the engagement agreed with the Ecodesign Steering Committee Secretariat (COCIR), which comprises the attached General Terms of Engagement for Wirtschaftsprüfer and Wirtschaftsprüfungsgesellschaften as of 1 January 2002, which are also applicable to third parties.

Munich, 2 September 2015

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Hendrik Fink Wirtschaftsprüfer (German Public Auditor) ppa. Heinke Richter

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