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To whom it may concern

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Your letter of
Our reference
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Information regarding removal of CE-mark for X-ray components by Siemens Healthcare GmbH

Ladies and gentlemen,

Triggered by the new Medical Device Regulation (MDR, (EU) 2017/745) the requirements for medical devices have been significantly changed. This impacts specifically the interpretation if a component can be a medical device on its own. For such components the supporting evidence cannot be provided in full to satisfy all requirements to be a medical device on its own. Consequently, a CE mark for such components cannot be obtained going forward under EU MDR.

Examples for such components of diagnostic X-ray systems manufactured by Siemens Healthcare GmbH would be

- high voltage generators,
- X-ray tube assemblies including single tank tube assemblies,
- multileaf collimators,
- wall- and ceiling-stands,
- detectors like image intensifiers,
- patient tables for diagnostic systems
- and grids.

In detail: With the new MDR the requirements for the technical documentation of medical devices have changed. Going along with this, the supporting evidence to proof compliance is more comprehensive than under the EU Medical Device Directive (MDD). As a result, stand-alone components for diagnostic X-ray systems less meet the definition of a medical device anymore as the diagnostic purpose of the component cannot be proven without system. Therefore, we Siemens Healthcare GmbH decide to not continue CE marking of the components for X ray devices in the future.

Key considerations on revised expected compliance aspects are:

Clinical evaluation report:

A component of a diagnostic X-ray system itself has nor clinical effect neither side effect. Therefore, possible side effects cannot be distinguished from the ones of the system. This is also true for probable contra-indications. The

system integrator has full ownership and responsibility defining the clinical purpose of the complete system including a comprehensive evaluation of the major components of his device.

Intended Purpose:

The intended purpose of a component for a diagnostic X-ray system can only be deployed within the system itself. For example, an X-ray tube assembly only can provide X-ray radiation in combination with a high voltage generator and the application of the radiation is controlled by the system application software.

The components mentioned above, are not distributed to end users (clinics or doctors) but to system integrators with the purpose of integrating those in their medical devices systems (business to business) only. Those medical device systems fall under the definition of a medical device following MDD and MDR and therefore need to fulfill the respective requirements.

Based on this, Siemens Healthcare GmbH, Technology Centers decided to not issue an EC Declaration of Conformity under EU MDR for components and to invalidate the EC Declaration of Conformity under Medical Device Directive 93/42/EEC. Therefore, those components will not be CE-marked anymore and not regarded as medical devices anymore in the EU but as components.

With kind regards,

Siemens Healthcare GmbH

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