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To who it may concern,

November 24, 2016

Bayer Medical Care Inc., 1 Bayer Drive, Indianola, PA15051, USA, markets the devices listed below.

Philips has performed compatibility tests at their site utilizing a limited number of samples in July 2016. The units used in testing are listed below:

MRI System		<3 rd party components>	
Product	Product number	Product	Product number
Ingenia 1.5T S	TB 10 R5	MEDRAD® MRXperion MR Injection system	Serial numbers 100144 100145
Ingenia 3.0T	Tb 12 R5	---	---

Through the basic compatibility testing with Bayer Medical Care Inc., products stated, Philips found MRI systems performed as intended and specified, with no detrimental degradation of system efficacy or safety when used per the conditions as stated in the Instructions for Use. This testing indicates compatibility of the Bayer Medical Care Inc. products with their respective Philips MRI systems.

Compatibility is limited to the models verified including the respective software revisions and does not apply to other models/software revisions, units, lots or batches of Bayer Medical Care Inc. or MRI devices.

Explicit exclusion from this compatibility statement are the Philips Achieva 1.5T and 3T systems, the Achieva d-Stream 1.5T and 3T systems and the Ingenia CX 1.5T and 3T systems.

Safety and efficacy of the Bayer Medical Care Inc. devices are the sole responsibility of Bayer Medical Care Inc. . All issues related to the use of Bayer Medical Care Inc. products shall be referred to Bayer Medical Care Inc. . This compatibility statement does not guarantee assurance that compatibility will be maintained with future software releases incorporated in the devices; any modifications or upgrades invalidate compatibility until testing reconfirms compatibility.

Compatibility testing reference file: TR MR Compatibility Bayer, DEP128095.

Anissa J. Hausaker
29 Nov 2016

MR Head of Q&R

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