



To whom it may concern

Maastricht, December 1, 2020

DECLARATION

Bayer's ongoing goal is to provide high quality and safe diagnostic imaging products to its customers so they can, in turn, provide high quality and safe patient care with every power injected CT, MRI, Molecular Imaging or cardiovascular examination.

It is important to us that our customers have absolute confidence in the safe utilization of our products. That's why *Medrad*® disposable products (syringes, tubing, and transfer devices) have been specifically designed, manufactured and validated to work reliably with corresponding *Medrad*® injection and PET Infusion systems contributing to optimal patient care.

The disposable products have unique technological design features developed to foster product safety and provide operational and clinical procedural benefits when used with the appropriate *Medrad*® injection or PET Infusion system. Specific materials, packaging configurations, manufacturing processes and sterilization methods were designed and developed to ensure the highest quality of each *Medrad*® disposable kit. Bayer's high quality manufacturing standards are embodied in the Operation Manuals of our Injection and PET Infusion Systems and we would like to emphasize the following warnings and recommendations to foster patient safety:

- Patient injury could result from leaks or ruptures during an injection. To prevent leaks or ruptures in the event of a blockage, use only disposable products from Bayer, or use catheters and connectors with pressure ratings compatible with this system.

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- Patient injury could result from using improper accessories. Use only accessories and options provided by Bayer designed for this system.


Bayer Medical Care B.V., European Authorized Representative of the manufacturer Bayer Medical Care Inc., 1 Bayer Drive, Indianola, P.A. 15051-0780, United States of America, hereby declares that **our own manufactured disposables for the Medrad® Injection System and PET Infusion System have been validated and verified (V&V) to work compatibly with our own manufactured Injection systems**, to comply with the EU MDR/ Article 22 requirements.

Bayer has not tested the compatibility of non-Bayer disposables with our injector systems, and therefore, cannot guarantee the mutual compatibility of these medical devices. If syringes are used for the calibration of Bayer Medrad® Injection Systems or PET Infusion Systems in the field, only original Bayer syringes are used.

Bayer assumes no liability for any clinical, safety and technical failure of the Medrad® Injection and PET Infusion Systems resulting from the use of non-Bayer disposables and consequently, failure caused by non-Bayer disposables are excluded from Bayer's equipment warranty.

Please refer any questions that you may have on the quality and safe use of Bayer's disposable kits to your local Bayer business partner. Bayer also offers training on the Medrad® Injection and PET Infusion Systems, however, for quality and safety reasons any such training will be provided only with original Bayer disposables compatible with the Medrad Injection or PET Infusion Systems.

For and on behalf of Bayer Medical Care B.V.


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