



Certification to deliver MAGNETOM Viato.Mobile in a trailer solution

Manufacturer: AMST by Kentucky Trailer
611 Commerce Center Drive
University Park, IL 60484, USA

MRI System: MAGNETOM Viato.Mobile with XJ gradient configuration


Building Type: Trailer solution

Test Results against SIEMENS SPECIFICATIONS


- Confirmation that SIEMENS MR Planning Guide has been carried out
- All requirements for MAGNETOM Viato.Mobile have been verified
- Documentation of all necessary steps for transportation
- Documentation of all requirements for safe transportation
- Documentation of responsibilities for end user
- Documentation of proper placement and operation of trailer solution
- MAGNETOM Viato.Mobile performs as specified in trailer solution

We hereby issue to the manufacturer a certification to deliver the above-mentioned building for the combined use with the above-mentioned Siemens MRI unit.

Erlangen, February 23, 2024


pp.a. *A. Schneck*
Electronically signed by:
Andreas Schneck
Reason: Document
Execution
Date: Mar 1, 2024 18:13
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Andreas Schneck
Head of Business Line MR


J. Teiche
Electronically signed by:
Joerg Teiche
Reason: Document
Execution
Date: Mar 1, 2024 10:08
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Jörg Teiche
Head of Quality&Technologies

Siemens Healthineers

DISCLAIMER: THE CERTIFICATION SHALL BECOME INVALID AS SOON AS THE MANUFACTURER MAKES ANY CHANGES TO HIS PRODUCTS THAT DO NOT MEET THE SPECIFICATIONS. THE CERTIFICATION CAN ALSO CEASE TO BE VALID IF THE MANUFACTURER BECOMES AWARE OF CUSTOMER COMPLAINTS WHICH CAN BE ATTRIBUTED TO COMBINED USE. THE MANUFACTURER SHALL BE OBLIGED TO INFORM SIEMENS WITHOUT DELAY WHENEVER HE BECOMES AWARE OF ANY SUCH COMPLAINTS, OR WHENEVER HE MAKES ANY CHANGES TO HIS PRODUCT THAT DO NOT MEET THE SPECIFICATIONS. THE MANUFACTURER SHALL BE OBLIGED TO SOLVE ANY CUSTOMER COMPLAINTS REGARDING HIS PRODUCTS. SIEMENS SHALL BE ENTITLED TO REVOKE THE CERTIFICATION, GIVING THE REASONS FOR DOING SO. POSSIBLE GROUNDS FOR DOING SO SHALL INCLUDE, BUT NOT BE LIMITED TO THE FOLLOWING: NEW COMPATIBILITY PROBLEMS WHICH HAVE ARISEN, CHANGES TO ANY OF THE MRI SYSTEMS NAMED IN THE CERTIFICATION, CUSTOMER COMPLAINTS IN CONNECTION WITH THE COMBINED USE. ALL COMMUNICATIONS BETWEEN THE MANUFACTURER AND SIEMENS SHALL BE MADE IN WRITING AND WITHOUT DELAY; ORAL (INCLUDING TELEPHONE) COMMUNICATIONS SHALL BE CONFIRMED IN WRITING WITHOUT DELAY. REGARDLESS OF WHETHER AND WHEN SIEMENS IS NOTIFIED, THE VALIDITY OF THE CERTIFICATE SHALL END ON THE DAY ON WHICH THE MANUFACTURER BECOMES AWARE OF A CUSTOMER COMPLAINT IN CONNECTION WITH THE COMBINED USE, MAKES CHANGES TO HIS PRODUCTS THAT DO NOT MEET THE SPECIFICATIONS, OR RECEIVES A REVOCATION FROM SIEMENS. THE MANUFACTURER SHALL INFORM HIS CUSTOMERS PROMPTLY OF THE CANCELLATION OF VALIDITY OF THIS. THIS CERTIFICATION IS NOT A DECLARATION OF COMPATIBILITY ACCORDING TO ARTICLE 12 OF COUNCIL DIRECTIVE 93/42/EEC OR ARTICLE 22 OF EU MDR 2017/745.