



Certificate for Software Evolution
VITEK® 2 Version 9.04 Software Release

Dear bioMérieux Customer,

The VITEK® 2 version 9.04 software release adds knowledge base updates pertaining to redeveloped drugs, analysis modifications, and breakpoints.

Additional information is available in the VITEK® 2 version 9.04 software release Customer Communication.

All activities for development, verification, and validation of the VITEK® 2 version 9.04 software release meet the requirements of the bioMérieux Quality Management System including Design Control procedures which are based on the following standards:

- ISO 9001: 2015
- NF ISO EN 13485: 2016
- QSR (Quality System Regulation) FDA - 21 CFR part 820
- (EU) IVDR 2017/746

Information regarding bioMérieux product development and test results, and the procedures used to develop, verify and validate, are proprietary and not available for distribution. This information is on file at bioMérieux and is available for review by appropriate regulatory agencies.

bioMérieux certifies the VITEK® 2 version 9.04 software release satisfied verification and validation acceptance criteria required to meet the standards outlined above and verification and validation included regression testing.

Based on the elements above, the laboratory is responsible for deciding to perform, or not perform, a system qualification, depending on its own risk analysis or local applicable regulations / practices.

Under no circumstances can bioMérieux undertake the activity of performing a laboratory's qualification.

Thank you,

Doreen Martin, Quality Assurance Representative

Confidential Information