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## Certification

We hereby certify that the software PrepCon5 (version 5.07.00 or higher) has been developed and tested in a manner consistent with the requirements for validation and operation in FDA regulated industries. It incorporates features that can provide technical compliance with 21 CFR Part 11 when implemented and operated in accordance with that regulation.

This applies also to OEM versions of the PrepCon5 software (version 5.07.00 or higher) including the Labomatic LaboChrom5 software and the Knauer Purity-Chrom software.

This certificate also applies to the SMB version of the OEM software, Purity-Chrom MCC (Version 5.09.021 or higher).

## Logfiles in PrepCon5/PurityChrom

In particular the software saves detailed run protocols during execution of a separation. These audit trails saved during separations include information on all executed commands, details of the fractionation, autosampler injections, loading, starting, stopping or restarting of methods, error messages and log entries for all manual command. The current version of the software ( 5.9.3x ) does not yet contain a general audit trail covering interactions between separations or failed login attempts, wrong passwords .

Weyhe, 18.09.2019



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- Geschäftsführer -