

SOFTWARE LICENSE AGREEMENT

[PyroMAT[®] Product Specific Validation \(PSV\) software](#)

[PyroMAT[®] Method 1 software](#)

[PyroMAT[®] Method 2 software](#)

SOFTWARE LICENCE AGREEMENT

PyroMAT® Product Specific Validation (PSV) software

This software license agreement ("**Agreement**") represents the terms and conditions between the user of the two different PyroMAT® PSV software solutions ("**Licensee**") and Merck KGaA, Frankfurter Straße 250, 64293 Darmstadt as the owner of the PyroMAT® PSV software solutions ("**Licensor**").

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The two different PyroMAT™ PSV software solutions comprise PyroMAT® PSV_I_II_III and PyroMAT® PSV_IV (hereinafter together the "**PyroMAT® PSV Software**"). The PyroMAT® PSV Software is proprietary software developed and owned by Licensor and protected under German Copyright Law and corresponding copyright laws worldwide.

Licensee wishes to implement and use the monocyte activation test for pyrogen detection (the "**Monocyte Activation Test**") by using the PyroMAT® PSV Software.

The PyroMAT® PSV Software can be downloaded on the Licensor's website. The PyroMAT® PSV Software has been developed and designed for assisting Licensee to analyze the data generated through the Monocyte Activation Test using PyroMAT® System.

The PyroMAT® PSV Software is only permitted to be used by Licensee in connection with Gen5 Software from Agilent Technologies, Inc. ("**Gen5**").

By clicking on the "Confirmation" button and the subsequent download of PyroMAT® PSV software on your computer device, you as Licensee enter into this Agreement with Licensor. The download of PyroMAT® PSV software by any other means is strictly prohibited.

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2. If third parties are entitled to such rights and they pursue these, then Licensor shall do everything in its power, in order to defend the PyroMAT® PSV software at its own expenses against third party rights claimed.

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Licensor provides support services for the PyroMAT® PSV Software within normal working hours: Monday to Friday (excluding bank holidays) 09.00 – 17:00 hours. Licensee can refer to the Licensor's website to access the contact information.

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SOFTWARE LICENCE AGREEMENT

PyroMAT® Method 1 software

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The PyroMAT® software has been developed by Licensor and comprises a range of different protocols for different methods of analysis to be used in connection with the different configurations of the proprietary software Gen5 from Agilent Technologies, Inc ("**Gen5**") in order to perform a Monocyte Activation Test.

PyroMAT® software protocols follow the methods and the product specific validations presented in the Monocyte Activation Test Chapter of the European Pharmacopeia (see Chapter 2.6.30) in order to check the validation criteria of each method or Product Specific Validations and provide conclusions of the test.

The different protocols of the PyroMAT® software can be downloaded on the Licensor's website separately. This Agreement relates solely to PyroMAT® Method 1 software as one of the available protocols of the PyroMAT® software, which is specifically designed for analyzing the results of the assay performed following Method 1 from European Pharmacopeia using PyroMAT® System (PyroMAT® Kit and PyroMAT® Cells).

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PyroMAT® Method 2 software

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The PyroMAT® software has been developed by Licensor and comprises a range of different protocols for different methods of analysis to be used in connection with the different configurations of the proprietary software Gen5 from Agilent Technologies, Inc. ("**Gen5**") in order to perform a Monocyte Activation Test.

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The different protocols of the PyroMAT® software can be downloaded on the Licensor's website separately. This Agreement relates solely to PyroMAT® Method 2 software as one of the available protocols of the PyroMAT® software, which is specifically designed for analyzing the results of the assay performed following Method 2 from European Pharmacopeia using PyroMAT® System (PyroMAT® Kit and PyroMAT® Cells).

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