SOFTWARE LICENSE AGREEMENT

PyroMAT™ Product Specific Validation (PSV) software

PyroMAT™ Method A software

PyroMAT™ Method B software

PyroMAT™ Method C software

SOFTWARE LICENCE AGREEMENT

PyroMAT™ Product Specific Validation software

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

I.   GENERAL

The three different PyroMAT™ PSV software solutions comprise PyroMAT™ PSV_I_II_III_A, PyroMAT™ PSV_I_II_III_B 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 BioTek Instruments 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.

II.   SCOPE OF LICENSE

1.   The use of the PyroMAT™ PSV Software other than in connection with Gen5 is strictly prohibited. Gen5 is a proprietary software owned by BioTek Instruments Inc. (www.biotek.com) and protected under German Copyright Law and corresponding copyright laws worldwide. Licensee has to acquire and obtain a license of Gen5 from BioTek Instruments Inc. in order to use the PyroMAT™ PSV software.

2.   Licensor hereby grants to Licensee a non-exclusive, non-transferable and non-sub-licensable right to use the PyroMAT™ PSV Software without any limitation in time and territory. The PyroMAT™ PSV Software may only be used in connection with Gen5 for the purposes of analyzing data generated through the Monocyte Activation Test using PyroMAT™ System. The use of the PyroMAT™ PSV Software in connection with other third party software is not permitted.

3.   No more extensive rights to use and exploit the PyroMAT™ PSV Software are granted to Licensee.

4.   The service fee payable by Licensee for the Product Specific Validation Services also includes the licensee fee for the use of the PyroMAT™ PSV Software.

5.   Licensee may not reverse engineer, decompile, modify or reassemble the PyroMAT™ PSV Software in whole or in parts in excess of the scope of mandatory laws, e.g. section 69e UrhG (German Copyright Act).

6.   Licensor is not obliged to provide Licensee with the underlying source code or associated development documentation in relation to the PyroMAT™ PSV Software.

III.   DUTIES OF LICENSEE

1.   Copyright notices, serial numbers and other identification features of the PyroMAT™ PSV Software may not be removed from the software or altered in any way.

2.   Licensee alone is responsible for the provision of the appropriate system environment in accordance with the systems requirements for the interoperability of the PyroMAT™ PSV Software with Gen5, in particular Licensee must have a valid license from BioTek Instruments Inc. to use Gen5.

3.   Licensee shall take appropriate precautions to protect the PyroMAT™ PSV Software against unauthorized use and access by third parties.

IV.   RIGHTS IN CASE OF DEFECTS

1.   The PyroMAT™ PSV Software shall be substantially in accordance with its product description. In case of defects, Licensee is entitled to alternative performance in the form of subsequent improvement or delivery of a conforming software version of the PyroMAT™ PSV Software.

2.   Defects must be notified in text form (e.g. e-mail) with a comprehensible description of the error symptoms, as far as possible evidenced by hard copies or other documents demonstrating the defect. The notification of the defect should enable the reproduction of error.

3.   Any claims for damages are subject to the limitations set forth in Section VII.

4.   Warranty claims shall be time-barred after 12 months of the transfer of risk.

V.   RIGHTS IN CASE OF DEFECTS IN TITLE

1.   The PyroMAT™ PSV Software shall be free from third party rights, which prevent the use in the scope of this Agreement.

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.

3.   To the extent that there are defects in title, Licensor is entitled at its option to either (i) take legitimate measures to remove the third party rights, which impair the contractual use of the PyroMAT™ PSV Software, or (ii) remedy the enforcement of such claims, or (iii) change or replace the PyroMAT™ PSV Software in such a manner, that it no longer infringes the rights of third parties.

4.   Section VI.4 applies accordingly.

VI.   SUPPORT SERVICES

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.

VII.   LIMITED LEGAL LIABILITY

1. Licensor shall be liable under this Agreement only in accordance with the provisions set out under (a) to (d).

    a) Licensor shall be unrestricted liable for losses caused intentionally or with gross negligence.

    b) Licensor shall be unrestricted liable for death, personal injury or damage to health caused by the intent or negligence of Licensor.

    c) Licensor shall be liable in accordance with the German Product Liability Act in the event of product liability.

    d) Licensor shall be liable for losses caused by the breach of its primary obligations. Primary obligations are such basic duties which form the essence of the Agreement, which were decisive for the conclusion of the Agreement and on the performance of which Licensee may rely. If Licensor breaches its primary obligations through simple negligence, then its ensuing liability shall be limited to the amount which was foreseeable by Licensor at the time the respective services was performed.

2. Any more extensive liability of Licensor is excluded on the merits.

VIII.   FINAL PROVISIONS

1. If any provision of this Agreement should be or become invalid, either completely or in part, this shall not affect the validity of the remaining provisions of this Agreement. The parties undertake instead to replace the invalid provisions with a valid provision which comes as close as possible to the purpose originally intended.

2. Insofar as Licensee is a merchant within the meaning of the German Commercial Code (HGB) or corporate body under public law or special fund under public law the place of jurisdiction and place of performance is Darmstadt, Germany. However, Licensor reserves the right to sue Licensee at Licensee's place of residence or place of business.

3. This Agreement is governed by the laws of the Federal Republic of Germany with the exclusion of the UN Sales Convention.

Should you have any questions concerning the use of the PyroMAT™ PSV Software or the terms and conditions of this Agreement, please refer to the Licensor's website for access to the contact information.

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SOFTWARE LICENCE AGREEMENT

PyroMAT™ Method A software

This license agreement ("**Agreement**") represents the terms and conditions between the user of the PyroMAT™ Method A software ("**Licensee**") and Merck KGaA, Frankfurter Straße 250, 64293 Darmstadt, as the owner of the PyroMAT™ Method A software ("**Licensor**").

I.   GENERAL

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 BioTek Instruments 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 A 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 A from European Pharmacopeia using PyroMAT™ System (PyroMAT™ KIT and PyroMAT™ CELLS).

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II.   SUBJECT MATTER OF THE LICENSE AGREEMENT

1.   The subject matter of the license granted under this Agreement is the PyroMAT™ Method A software in its version provided for a download on Licensor's website.

2.   PyroMAT™ software is a proprietary software developed and owned by Licensor and protected under German Copyright Law and corresponding copyright laws worldwide.

3.   Gen5 is a proprietary software owned by BioTek Instruments Inc. (www.biotek.com) and protected under German Copyright Law and corresponding copyright laws worldwide.

III. SCOPE OF LICENSE

1. The use of PyroMAT™ Method A software other than in connection with Gen5 is strictly prohibited. Licensee has to acquire and obtain a license of a version of Gen5 from BioTek Instruments Inc. in order to use PyroMAT™ Method A software as a complementary product in the scope of use of Gen5.

2. Licensor hereby grants to Licensee a non-exclusive, non-transferable and non-sub-licensable right to use PyroMAT™ Method A software as a complementary software product together with Gen5 without any limitation in time and territory. PyroMAT™ Method A software may only be used in connection with Gen5 for the purposes of analyzing data generated with pyrogen detection assays. The use of PyroMAT™ Method A software in connection with other third party software is not permitted.

3. The software license under this Agreement is provided by Licensor free of charge.

4. Licensee may not reverse engineer, decompile, modify or reassemble PyroMAT™ Method A software in whole or in parts in excess of the scope of mandatory laws, e.g. section 69e UrhG (German Copyright Act).

5. Licensor is not obliged to provide Licensee with the underlying source code or associated development documentation in relation to PyroMAT™ Method A software.

6. No more extensive rights to use and exploit PyroMAT™ Method A software are granted to Licensee.

IV. DUTIES OF LICENSEE

1. Copyright notices, serial numbers and other identification features of PyroMAT™ Method A software may not be removed from the software or altered in any way.

2. Licensee alone is responsible for the provision of the appropriate system environment in accordance with the systems requirements for the interoperability of PyroMAT™ Method A software with Gen5, in particular Licensee must have a valid license from BioTek Instruments Inc. to use Gen5.

3. Licensee shall take appropriate precautions to protect PyroMAT™ Method A software against unauthorized use and access by third parties.

4. In respect of any future updates, upgrades and new versions of PyroMAT™ Method A software, Licensee alone shall be responsible for the installment of such updates, upgrades and new versions of PyroMAT™ Method A software in a timely manner, which will be also made available for download on Licensor's website.

V. DISCLAIMER OF WARRANTIES

1. The description of PyroMAT™ Method A software on Licensor's websites shall not be deemed as guaranteed with regard to PyroMAT™ Method A software.

2. A warranty (*Gewährleistung*) for defects in title and quality defects of PyroMAT™ Method A software is excluded. Licensor is only liable to compensate Licensee for any resulting damages incurred in connection with defects of title and defects of quality of PyroMAT™ Method A software fraudulently concealed by Licensor.

VI.   LIMITED LEGAL LIABILITY

1. Licensor shall be liable in connection with the provision of PyroMAT™ Method A software for losses caused intentionally or with gross negligence or in the event of death, personal injury or damage to health caused by the intent or negligence of Licensor.

2. Licensor is also liable in accordance with the German Product Liability Act.

3. Any more extensive liability of Licensor is excluded on the merits, in particular Licensor shall not be liable for any results, conclusions and the performance of PyroMAT™ Method A software outside the agreed scope of use under this Agreement. In addition, Licensor shall not be liable for any consequential, incidental or any other kind of damages resulting from economic loss or property damage sustained by Licensee in connection with the use of PyroMAT Method A software.

VII.   FINAL PROVISIONS

1. If any provision of this Agreement should be or become invalid, either completely or in part, this shall not affect the validity of the remaining provisions of this Agreement. The parties undertake instead to replace the invalid provisions with a valid provision which comes as close as possible to the purpose originally intended.

2. Insofar as Licensee is a merchant within the meaning of the German Commercial Code (HGB) or corporate body under public law or special fund under public law the place of jurisdiction and place of performance is Darmstadt, Germany. However, Licensor reserves the right to sue Licensee at Licensee's place of residence or place of business.

3. This Agreement is governed by the laws of the Federal Republic of Germany with the exclusion of the UN Sales Convention.

Should you have any questions concerning the use of PyroMAT™ Method A software or the terms and conditions of this Agreement, please refer to the Licensor's website for access to the contact information.

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SOFTWARE LICENCE AGREEMENT

PyroMAT™ Method B software

This license agreement ("**Agreement**") represents the terms and conditions between the user of the PyroMAT™ Method B software (**"Licensee")** and Merck KGaA, Frankfurter Straße 250, 64293 Darmstadt, as the owner of the PyroMAT™ Method B software ("**Licensor**").

I.   GENERAL

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 BioTek Instruments 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 B 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 B from European Pharmacopeia using PyroMAT™ System (PyroMAT™ KIT and PyroMAT™ CELLS).

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II.   SUBJECT MATTER OF THE LICENSE AGREEMENT

1.   The subject matter of the license granted under this Agreement is the PyroMAT™ Method B software in its version provided for a download on Licensor's website.

2.   PyroMAT™ software is a proprietary software developed and owned by Licensor and protected under German Copyright Law and corresponding copyright laws worldwide.

3.   Gen5 is a proprietary software owned by BioTek Instruments Inc. (www.biotek.com) and protected under German Copyright Law and corresponding copyright laws worldwide.

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1.   The use of PyroMAT™ Method B software other than in connection with Gen5 is strictly prohibited. Licensee has to acquire and obtain a license of a version of Gen5 from BioTek Instruments Inc. in order to use PyroMAT™ Method B software as a complementary product in the scope of use of Gen5.

2.   Licensor hereby grants to Licensee a non-exclusive, non-transferable and non-sub-licensable right to use PyroMAT™ Method B software as a complementary software product together with Gen5 without any limitation in time and territory. PyroMAT™ Method B software may only be used in connection with Gen5 for the purposes of analyzing data generated with pyrogen detection assays. The use of PyroMAT™ Method B software in connection with other third party software is not permitted.

3.   The software license under this Agreement is provided by Licensor free of charge.

4.   Licensee may not reverse engineer, decompile, modify or reassemble PyroMAT™ Method B software in whole or in parts in excess of the scope of mandatory laws, e.g. section 69e UrhG (German Copyright Act).

5.   Licensor is not obliged to provide Licensee with the underlying source code or associated development documentation in relation to PyroMAT™ Method B software.

6.   No more extensive rights to use and exploit PyroMAT™ Method B software are granted to Licensee.

IV.   DUTIES OF LICENSEE

1.   Copyright notices, serial numbers and other identification features of PyroMAT™ Method B software may not be removed from the software or altered in any way.

2.   Licensee alone is responsible for the provision of the appropriate system environment in accordance with the systems requirements for the interoperability of PyroMAT™ Method B software with Gen5, in particular Licensee must have a valid license from BioTek Instruments Inc. to use Gen5.

3.   Licensee shall take appropriate precautions to protect PyroMAT™ Method B software against unauthorized use and access by third parties.

4.   In respect of any future updates, upgrades and new versions of PyroMAT™ Method B software, Licensee alone shall be responsible for the installment of such updates, upgrades and new versions of PyroMAT™ Method B software in a timely manner, which will be also made available for download on Licensor's website.

V.   DISCLAIMER OF WARRANTIES

1.   The description of PyroMAT™ Method B software on Licensor's websites shall not be deemed as guaranteed with regard to PyroMAT™ Method B software.

2.   A warranty (*Gewährleistung*) for defects in title and quality defects of PyroMAT™ Method B software is excluded. Licensor is only liable to compensate Licensee for any resulting damages incurred in connection with defects of title and defects of quality of PyroMAT™ Method B software fraudulently concealed by Licensor.

VI.   LIMITED LEGAL LIABILITY

1.   Licensor shall be liable in connection with the provision of PyroMAT™ Method B software for losses caused intentionally or with gross negligence or in the event of death, personal injury or damage to health caused by the intent or negligence of Licensor.

2.   Licensor is also liable in accordance with the German Product Liability Act.

3.   Any more extensive liability of Licensor is excluded on the merits, in particular Licensor shall not be liable for any results, conclusions and the performance of PyroMAT™ Method B software outside the agreed scope of use under this Agreement. In addition, Licensor shall not be liable for any consequential, incidental or any other kind of damages resulting from economic loss or property damage sustained by Licensee in connection with the use of PyroMAT Method B software.

VII.   FINAL PROVISIONS

1.   If any provision of this Agreement should be or become invalid, either completely or in part, this shall not affect the validity of the remaining provisions of this Agreement. The parties undertake instead to replace the invalid provisions with a valid provision which comes as close as possible to the purpose originally intended.

2.   Insofar as Licensee is a merchant within the meaning of the German Commercial Code (HGB) or corporate body under public law or special fund under public law the place of jurisdiction and place of performance is Darmstadt, Germany. However, Licensor reserves the right to sue Licensee at Licensee's place of residence or place of business.

3.   This Agreement is governed by the laws of the Federal Republic of Germany with the exclusion of the UN Sales Convention.

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SOFTWARE LICENCE AGREEMENT

PyroMAT™ Method C software

This license agreement ("**Agreement**") represents the terms and conditions between the user of the PyroMAT™ Method C software **("Licensee")** and Merck KGaA, Frankfurter Straße 250, 64293 Darmstadt, as the owner of the PyroMAT™ Method C software ("**Licensor**").

I. GENERAL

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 BioTek Instruments 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 C 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 C from European Pharmacopeia using PyroMAT™ System (PyroMAT™ KIT and PyroMAT™ CELLS).

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2. PyroMAT™ software is a proprietary software developed and owned by Licensor and protected under German Copyright Law and corresponding copyright laws worldwide.

3. Gen5 is a proprietary software owned by BioTek Instruments Inc. (www.biotek.com) and protected under German Copyright Law and corresponding copyright laws worldwide.

III. SCOPE OF LICENSE

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2. Licensor hereby grants to Licensee a non-exclusive, non-transferable and non-sub-licensable right to use PyroMAT™ Method C software as a complementary software product together with Gen5 without any limitation in time and territory. PyroMAT™ Method C software may only be used in connection with Gen5 for the purposes of analyzing data generated with pyrogen detection assays. The use of PyroMAT™ Method C software in connection with other third party software is not permitted.

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V. DISCLAIMER OF WARRANTIES

1. The description of PyroMAT™ Method C software on Licensor's websites shall not be deemed as guaranteed with regard to PyroMAT™ Method C software.

2. A warranty (*Gewährleistung*) for defects in title and quality defects of PyroMAT™ Method C software is excluded. Licensor is only liable to compensate Licensee for any resulting damages incurred in connection with defects of title and defects of quality of PyroMAT™ Method C software fraudulently concealed by Licensor.

VI.   LIMITED LEGAL LIABILITY

1. Licensor shall be liable in connection with the provision of PyroMAT™ Method C software for losses caused intentionally or with gross negligence or in the event of death, personal injury or damage to health caused by the intent or negligence of Licensor.

2. Licensor is also liable in accordance with the German Product Liability Act.

3. Any more extensive liability of Licensor is excluded on the merits, in particular Licensor shall not be liable for any results, conclusions and the performance of PyroMAT™ Method C software outside the agreed scope of use under this Agreement. In addition, Licensor shall not be liable for any consequential, incidental or any other kind of damages resulting from economic loss or property damage sustained by Licensee in connection with the use of PyroMAT Method C software.

VII.   FINAL PROVISIONS

1. If any provision of this Agreement should be or become invalid, either completely or in part, this shall not affect the validity of the remaining provisions of this Agreement. The parties undertake instead to replace the invalid provisions with a valid provision which comes as close as possible to the purpose originally intended.

2. Insofar as Licensee is a merchant within the meaning of the German Commercial Code (HGB) or corporate body under public law or special fund under public law the place of jurisdiction and place of performance is Darmstadt, Germany. However, Licensor reserves the right to sue Licensee at Licensee's place of residence or place of business.

3. This Agreement is governed by the laws of the Federal Republic of Germany with the exclusion of the UN Sales Convention.

Should you have any questions concerning the use of PyroMAT™ Method C software or the terms and conditions of this Agreement, please refer to the Licensor's website for access to the contact information.

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