

General Terms and Conditions of DEKRA Certification GmbH for the business field of medical devices

§ 1 / General - Scope

These terms and conditions are valid for all contractual legal relationships between DEKRA Certification GmbH ('DEKRA') and the client. Contradictory or discrepant conditions of the client will not be accepted unless they are confirmed expressly in writing. These terms and conditions are also valid in the version then in force for follow-up orders and ongoing business relationships.

§ 2 / Order confirmation

A contract is agreed between DEKRA and the client if the client accepts an offer from DEKRA within the validity period of that offer or if DEKRA has confirmed an order from the client.

§ 3 / Client obligations

1. The client must provide DEKRA with all the necessary information and documents for the execution of the order in full, on time and free of charge.

2. The client must notify DEKRA of his own accord of all processes and circumstances that could be significant for the execution of the order.

3. The client must carry out all necessary preparations at its own responsibility and on its own account; the necessary information for this is available from DEKRA. In the event that an auxiliary person is necessary for the execution of tests (e.g. to tour premises) then the auxiliary person is appointed and coordinated by the client.

4. In the event that the order cannot be carried out by the agreed date for a reason for which the client is responsible then DEKRA reserves the right to charge the client for the resulting damage; this is generally the order value minus saved expenses (each in relation to the relevant date) and is calculated as follows:

- If the date cancellation takes place at the latest 14 calendar days before the agreed date then 20 percent of the order value is charged.
- If the date cancellation takes place at the latest 5 calendar days before the agreed date then 50 percent of the order value is charged.
- If the date cancellation takes place fewer than 5 calendar days before the agreed date then the full order value is charged.

DEKRA reserves the right to claim damages actually incurred. In each of the above cases the client is permitted to prove that damage either did not occur or was less than charged.

5. If delays are caused to an agreed date on the grounds of breach of duty by the client then DEKRA reserves the right to charge additional costs at the agreed – alternatively, to the standard – hourly rate.

§ 4 / DEKRA's obligations

1. DEKRA will provide the contractual services impartially, neutrally and to the best of its knowledge and belief. Where applicable the recognised codes of practice will be taken into account as exist at the time the contract is agreed.

2. If the agreed scope of the order is modified or extended in the course of its execution then the agreed remuneration will be adjusted accordingly.

§ 5 / Confidentiality, data use/protection

1. DEKRA will not disclose reports or other facts and documents of which it gains knowledge while executing the contractual services and that refer to the client or the object of the order to unauthorised person or use or disclose the same. The following are excepted:

- Anonymised processing of the statistical data by DEKRA;
- Disclosure obligations in accordance with an accreditation body's regulations;
- Disclosure to safeguard own legitimate interests;
- Statutory, court-ordered or official disclosure obligations.

2. For their own files, DEKRA is permitted to make copies of the written documents that were provided to DEKRA for inspection or in order to execute the order.

3. DEKRA will save, process and use person-specific data from the client for the orderly fulfilment of the order and for their own purposes. In the event that automated data processing systems are used for this purpose then DEKRA guarantees compliance with the requirements of the federal data protection act (BDSG). Personnel who work on data processing are compelled by the BDSG and obliged to comply with all data protection regulations.

§ 6 / Usage rights

1. In the event that results are produced during the execution of the order that are subject to copyright (e.g. reports, test results, calculations) then DEKRA grants the client simple, non-exclusive, non-transferable and non-sublicensable usage rights if and to the extent as necessary for contract purposes.

2. The client may only use the result in full, not in extract form and only for the agreed purpose.

§ 7 / Guarantee

1. DEKRA is entitled to improve or repeat inadequate services (collectively 'supplementary performance'). The client must set a reasonable period for fulfilment. In the event that and only if the supplementary performance has been finally and seriously rejected, not undertaken by the due date or has failed then the client is entitled to his choice of price reduction or withdrawal within the provisions of the law.

2. The client must notify DEKRA immediately after discovery of any complaints. The guarantee period ends one year after the onset of the statutory period of limitations except if DEKRA has maliciously concealed the defects.

§ 8 / Payment conditions

1. The remuneration is understood plus statutory value-added tax at the then valid level. The turnover tax is listed separately in the invoice.

2. Remuneration should be regulated in the offer or the order confirmation. If this does not take place then the relevant valid DEKRA fee ordinance is valid - insofar as this is known or should be known to the client – or the standard remuneration.

3. As part of the continuous obligation any increases in remuneration must be announced by DEKRA three months in advance. They entitle the client to cancel with one month's notice to the date of the increase.

4. The client's right to retention of the remuneration or to offset remuneration against a counterclaim is precluded except if the counterclaim is undisputed or recognised by declaratory judgement.

5. DEKRA is entitled to demand advance payment of costs – if there are actual grounds and these are not countered by overriding concerns of the client – or partial invoices in accordance with services already provided. If the client is in arrears with the payment of at least one partial invoice despite deadline extension then DEKRA is entitled to refuse further execution of the order, withdraw from the contract and/or demand compensation in place of delivery.

§ 9 / Termination of the contract

1. If the contract provides for services over a number of years, the right to termination is precluded during the term of the contract. The contract can be terminated by either party at any time in writing for good cause. In particular DEKRA is entitled to withdraw for good reason if

- The client refuses necessary cooperation – even after having been demanded to cooperate within a reasonable period.
- The client attempts to falsify the result of the order.
- Insolvency proceedings are opened on the client's assets or if the same is rejected due to lack of assets.
- The client has not paid a due invoice within a reasonable period despite a reminder.

2. In the event of termination for a material reason for which DEKRA is not responsible, DEKRA retains the claim to remuneration as for performance of the contractually stipulated service until the end of the term of the contract. Taking into account any saved costs the remuneration will be 15% of the remuneration of the services not yet provided by DEKRA except if the client can prove lesser contractual work or higher savings.

3. In the cases named above in 9.1 DEKRA may also refuse to provide further services at its own discretion. The right to withdraw is not affected.

§ 10 / Liability

1. DEKRA is liable without limitation for damage caused by injury to life, body or health or other damage caused by the intentional or grossly negligent violation of the obligation of a legal or vicarious agent of DEKRA.

2. In the event of negligent breach of a material duty the obligation to pay compensation is limited to damage foreseen as typical for the contract when the contract was agreed. Essential contractual obligations are obligations that must be fulfilled to make the contract possible and that put the purpose of the contract at risk if violated and that the contractual partners rely on regularly. For this contract the parties limit the foreseeable, typical damage to a maximum of EUR 2,500,000 per claim.

3. Any further liability by DEKRA is excluded.

4. The client must notify DEKRA immediately and in writing of any damage for which DEKRA must pay.

5. Where compensation claims against DEKRA are excluded this is also valid for the personal liability of DEKRA employees.

6. Compensation claims in accordance with § 10 item 1 come under the statute of limitations in accordance with statutory regulations. Compensation claims in accordance with § 10 item 2 come under the statute of limitations one year after onset of the statutory period of limitations.

§ 11 / Final provisions

1. The contract, modifications, additions and subsidiary agreements of any kind must be produced in text form if no stricter form is required by law. The form requirements are also valid for changes to or the cancellation of this form clause.

2. The court of jurisdiction for claims of the parties is the headquarters of DEKRA wherever the prerequisites in § 38 ZPO are given. The place of fulfilment for all obligations arising from this contract is the headquarters of DEKRA insofar as the prerequisites in § 29 II ZPO are given.

3. The contractual relationship is governed exclusively by the substantive law of the Federal Republic of Germany. The UN sales convention does not apply.

4. In the event that one regulation in these terms and conditions is or becomes invalid or if a loophole is discovered then this will not affect the validity of the remaining regulations. In this case the client and DEKRA undertake to strive to agree a replacement regulation to achieve the intended purpose.

Stuttgart, January 2013