

General Certification Conditions (GCC) of DEKRA Certification GmbH for the business field of medical devices

1. Scope

- 1.1 These GCC are valid for all contractual relationships between the client and DEKRA Certification GmbH for services provided by DEKRA Certification GmbH, particularly in connection with the certification of quality management systems according to EN ISO 13485 and directives 93/42/EEC and conformity assessment procedures according to directives 93/42/EEC and regulation (EU) No. 722/2012 and services offered together with this e.g. certifications according to ISO 9001.
- 1.2 Furthermore the product-specific, applicable specific certification conditions are also valid.

2. Definitions

- 2.1 The term '**Accreditation Bodies/Designating Authorities**' is used to describe all bodies, notifying authorities, scheme owners and registration offices that have registered, notified or accredited DEKRA Certification GmbH for certification on the basis of laws, standards, regulations or contracts for the certification of clients, in particular but not limited to the German accreditation office - "Deutsche Akkreditierungsstelle" ('DAkkS'), and the Central Authority of the Federal States for Health Protection regarding Medicinal Products and Medical Devices - "Zentralstelle der Länder für Gesundheitsschutz bei Arzneimitteln und Medizinprodukten" ('ZLG').
- 2.2 The term '**audit**' is used in the following to describe all types of audits according to the relevant standards and Accreditation Bodies/Designating Authorities, for example initial certification audits, surveillance audits, recertification audits, follow-up audits, improvement controls, additional audits, audits for special reasons, repeat testing, repeat audits, supplementary audits, controls, follow-up controls, enhanced controls, inspections, witness test, observed audits, parallel audits, special audits and unannounced audits.
- 2.3 A DEKRA-seal is a seal awarded to the client in the format set in the **appendix** to these GCC.
- 2.4 The term '**internal audit**' describes an audit in which the client is audited based on requirements set by the client.
- 2.5 The term '**second party audit**' is used to describe an audit in which either third parties are audited based on requirements set by the client or the client is audited on the basis of requirements set by third parties that are not Accreditation Bodies/Designating Authorities.
- 2.6 '**Unannounced audits**' refer to such audits carried out by DEKRA Certification GmbH in accordance with the certification requirements without prior appointment with the client or prior notice to the client or third parties.
- 2.7 The term '**certificate**' is used in these GCC for certificates, certificates of conformity, confirmations and similar attestations (like e.g. design examination certificates) issued by DEKRA Certification GmbH.
- 2.8 '**Certification Requirements**' means any and all laws, standards, directives, regulations, rules, regimes and other requirements by a legislator or Accreditation Body, according to which DEKRA Certification GmbH assesses, audits and/or certifies.
- 2.9 '**Certification decision**' is the decision relating to certification including granting, refusing, maintaining of certification, expanding or reducing the scope of certification, renewing, suspending or restoring following suspension, or withdrawing of certification.
- 2.10 The term '**certification process**' is used for the process described in section 4 and includes the conformity assessment procedure, e.g. the conformity assessment procedure according to directive 93/42/EEC and regulation (EU) No. 722/2012.

3. Audits

3.1 Use of auditors/experts

- 3.1.1 DEKRA Certification GmbH is entitled to use both internal and external auditors and experts in order to provide auditing services.
- 3.1.2 DEKRA Certification GmbH undertakes to only use qualified and suitable auditors/experts who are appointed as DEKRA Certification GmbH auditors/experts.
- 3.1.3 The client receives information on the identity of the auditor/expert used only in the case of announced audits. In this case, the client is only entitled to reject an auditor used by DEKRA Certification GmbH if it is unreasonable to expect him to work with the auditor/expert or the auditor/expert is not suitable to provide the service for other important reasons. The client must notify DEKRA Certification GmbH of the rejection immediately and must provide reasons. In this event DEKRA Certification GmbH is obliged to use a different, suitable auditor/expert in place of the rejected auditor/expert.
- 3.1.4 In the event that an auditor/expert drops out immediately before or during the audit then DEKRA Certification GmbH will name a substitute within a reasonable period. Section 3.1.3 is valid accordingly for the rejection of this substitute.

3.2 Audit dates and deadlines

- 3.2.1 Except from unannounced audits the client can provide desired dates for the execution of the audit and this will be considered by DEKRA Certification GmbH against the background of capacities and practicability. Desired dates provided by the client are non-binding and need not be observed by DEKRA Certification GmbH. Except from unannounced audits DEKRA Certification GmbH and the client will agree binding dates in good time before the planned audit.
- 3.2.2 Audits are generally to be carried out fully within certain deadlines. DEKRA Certification GmbH will inform the client of the deadlines within which the audits need to be carried out. The client has the following obligations to cooperate in connection with these deadlines:
 - 3.2.2.1 The client will contact DEKRA Certification GmbH in good time in order to agree dates and will agree a date so that DEKRA Certification GmbH can complete the audit within the deadlines.
 - 3.2.2.2 The client will have an audit that has been begun carried out in full. If the client interrupts an audit that has been begun or if DEKRA Certification GmbH interrupts an audit that has already been begun and this interruption is for a reason that falls in the sphere of influence the client, then the audit is considered not to have been carried out.

In the event that the client fails to cooperate in the agreement of or adherence to audit dates and if it is therefore impossible for the audit to be performed or for it to be performed within the deadlines then DEKRA Certification GmbH is entitled to terminate the contract for good cause. Other compensation and other claims remain unaffected. DEKRA Certification GmbH is also entitled to suspend or withdraw a certificate or DEKRA-seal that has already been granted in accordance with the more detailed provisions in section 5.11.
- 3.2.3 In the event that serious incidents occur at the site or in the area in which DEKRA Certification GmbH is to carry out an audit, particularly force majeure, unrest, war or terrorist acts or if travel warnings are issued for the area by the German Federal Foreign Office then DEKRA Certification GmbH is released from its obligations to provide audit services for the duration of the disruption if they default. The contractual parties are obliged to inform each other of such hindrances and to adjust their obligations to the changed circumstances in good faith.

General Certification Conditions (GCC) of DEKRA Certification GmbH for the business field of medical devices

4. Certification process structure

4.1 Process structure

- 4.1.1 If the contract includes certification and the process structure is not regulated in a different way then the certification process comprises an initial certification audit for the initial issue of a certificate or a recertification certificate for the repeat issue of the certificate plus regular surveillance audits in the phases between initial certification and recertification or recertification and the next recertification.
- 4.1.2 If DEKRA Certification GmbH determines defects in the course of an audit and these are not resolved in time by the client as demanded by DEKRA Certification GmbH then DEKRA Certification GmbH is entitled to terminate the contract for good cause. Other compensation and other claims remain unaffected. DEKRA Certification GmbH is also entitled to suspend or withdraw a certificate or DEKRA-seal that has already been granted in accordance with the more detailed provisions in section 5.11.

4.2 Initial certification audits

- 4.2.1 A pre-audit can be arranged at the request of the client. The tests that are carried out in a pre-audit are generally tests of management documentation and random function tests on the management system. The pre-audit does not claim to determine all defects. Pre-audits can generally only be carried out once for each customer and standard. Further Accreditation Body/Designating authority regulations must be observed.
- 4.2.2 The initial certification audit is carried out in two stages, where the contract does not stipulate anything to the contrary, namely a readiness analysis with document inspection ('stage 1') and an on-site audit at the client's facility/facilities ('stage 2'). The audit report is produced after stage 2. The results of stage 1 can necessitate changes to the planning of stage 2, e.g. audit duration, composition of the audit, selection of the audit team members team or date of the audit. Stage 1 of the audit is usually also performed on site at the client's facility/facilities. It is also possible to mandate that phase 1 must be carried out again in full or in part subject to a charge. Phase 1 of the audit is generally also carried out on site / at the facility/facilities of the client.
- 4.2.3 No more than 6 months may pass between the end of stage 1 and the beginning of stage 2, if nothing is agreed to the contrary. If it is not possible to comply with this six-month deadline because of a reason for which the client is responsible then the client is obliged to pay for the repetition of stage 1. The client will receive a separate offer for this work.
- 4.2.4 6 months after the last day of Phase 2 the realisation of necessary corrections and correction measures must have been verified by the customer of DEKRA Certification GmbH. If it is not possible to adhere to this deadline of 6 months for a reason that falls within the sphere of influence of the client, then Phase 2 must be carried out again subject to a charge. The client will receive a separate offer for this.
- 4.2.5 The initial certification audit must have been started within one year of contract agreement.

4.3 Surveillance audits

During the validity of the certificate the client is obliged, in accordance with the contract and the regulations of the Accreditation Body/Designating authority or the law, to arrange for DEKRA Certification GmbH to perform surveillance audits within the given deadlines.

4.4 Recertification process

A recertification process must be performed for the extension of the certificate in accordance with the more detailed provisions in the contract, generally after 3 or 5 years. The recertification audit is equivalent to the process for the initial certification audit.

4.5 Follow-up audit, additional audit and unannounced audit

- 4.5.1 If defects, such as non-conformities are determined in the course of audits it is at the discretion of DEKRA Certification GmbH to carry out a follow-up audit. The costs are calculated according to expenditure and the up-to-date price list.
- 4.5.2 DEKRA Certification GmbH can direct additional audits, even if announced or unannounced at short notice. In particular this can occur if DEKRA Certification GmbH becomes aware of reasons for a possible withdrawal of the certificate, in order to review the implementation of corrective actions, in order to investigate complaints or after a change of laws, standards, guidelines or agreements upon which the certification is based. DEKRA Certification GmbH will produce a separate offer for the additional audit.
- 4.5.3 Follow-up audits, improvement controls and additional audits must be performed within the deadline named by DEKRA Certification GmbH
- 4.5.4 If and insofar as provided for in the certification requirements, DEKRA Certification GmbH can conduct unannounced audits while the certificate is valid. The client must cooperate in full with unannounced audits to allow DEKRA Certification GmbH to conduct the audit in accordance with certification requirements. The manufacturer must pay for the unannounced audits by DEKRA Certification GmbH in accordance with the up-to-date price list. DEKRA Certification GmbH will provide the client with a report on the unannounced audit against payment.

4.6 Witness audits / parallel audits / special audits

- 4.6.1 The client will allow the employees or agents of the Accreditation Bodies/Designating Authorities of DEKRA Certification GmbH to carry out observed audits, witness tests, parallel audits or special audits in all the client's operations. The client undertakes to ensure such observed audits, witness tests, parallel audits or special audits are possible at the client's manufacturers and subcontractors.

4.7 Certification decision

- 4.7.1 DEKRA Certification GmbH has the sole right to make the certification decision. DEKRA Certification GmbH will make the decision following orderly execution of the initial certification audit, the re-certification audit and/or the monitoring audit or additional audit. DEKRA Certification GmbH will take the certification decision at its own discretion within the constraints of applicable norms and regulations and based on the information and documents received in the course of the audit.
- 4.7.2 If the certification decision is positive then the client will receive a certificate and possibly a DEKRA-seal (only if explicitly included in the contract) in accordance with the detailed provisions of the contract or information that the client may maintain the certification.
- 4.7.3 If the certification decision is negative then the client will not receive a certificate because he does not fulfil all the prerequisites for the certificate to be issued. The client will be informed accordingly. In this case both parties are entitled to terminate the contract for good cause. Other compensation and other claims remain unaffected. DEKRA Certification GmbH is also entitled to suspend or withdraw a certificate or DEKRA-seal that has already been granted in accordance with the more detailed provisions in section 5.11.
- 4.7.4 Issuance of a certificate may be associated with conditions. For example it is possible that the resolution of defects can be demanded within a certain deadline so that the client must independently resolve defects and confirm this in writing. The condition could also be further inspection, i.e. a further audit or inspection of documentation.

5. Issuing and use of certificates, DEKRA-seals and documents

- 5.1 If the client is explicitly awarded with a certificate and possibly a DEKRA-seal or if test-related documents are made available to the client, e.g. reports (jointly 'usage object') then the client has the right to use the usage object in accordance with the following regulations.

General Certification Conditions (GCC) of DEKRA Certification GmbH for the business field of medical devices

- 5.2 DEKRA Certification GmbH retains ownership of the usage object and particularly of existing trademarks and copyrights. DEKRA Certification GmbH grants the client upon award with or provision with the usage object with the non-exclusive right to use it within the following scope.
- 5.3 If and insofar as the contract provides for a multisite procedure certification, the headquarters entity is granted the right to sub-license the right to use to the multisite members, if and to the extent that the multisite member accepts to adhere to these GCC as if the location itself were DEKRA Certification GmbH's client. The multisite member is not allowed to further sub-license the right to use. The client must immediately withdraw the sub-license given to a multisite member if a multisite member falls in one of the categories in section 5.11 of these GCC. The client shall immediately inform DEKRA Certification GmbH hereof. If a multisite member falls in one of the categories in section 5.11 of these GCC, DEKRA Certification GmbH is entitled to immediately withdraw the headquarters entity's right to sub-license the right to use to a multisite member. Other than as stated above, the client is not entitled to transfer or sub-license the usage right granted to him. The existence of the sub-license depends on passing the headquarters licence.
- 5.4 In the absence of other agreements, the usage object was designed for use in the country where DEKRA Certification GmbH has its legal headquarters: use abroad takes place at the sole responsibility of the client, thus the liability of DEKRA Certification GmbH is ruled out in this regard.
- 5.5 The usage object may only be used in the form in which it is issued and handed over. Changes, in particular to the design, colour or text are not permitted. The client is not entitled to use only extracts of the usage object, i.e. the usage object may only be used as a whole.
- 5.6 If the client also receives the usage object in electronic form then the client is entitled to change the size of the usage object; if reduced it can only be reduced to a minimum font size of Arial 4. In any case of size change the text in the usage object must remain fully legible and the proportion of text and symbol may not be altered.
- 5.7 The client must ensure the reference of the usage object to the subject of the test by only representing the usage object in such a way that the average consumer understands it as a mark of the tested, evaluated and/or certified activities, processes, systems or qualifications. The usage object may only be used in connection with the activities, processes, systems or qualifications for which the usage object was awarded and only in order to show that these activities, processes, systems or qualifications are in accordance with the requirements according to which they were tested, evaluated and/or certified. If the certification area is limited, then the illustration must be modified accordingly. The client may not use the usage object in order to advertise a product and may not give the impression that DEKRA Certification GmbH carried out a product test. The usage object may not be used for test objects changed since the test.
- 5.8 When the usage object is used the impression may not be given that the certification is valid for activities or locations outside the certification area.
- 5.9 The usage object may not be utilised or referenced in a way that could damage DEKRA Certification GmbH's reputation or could be seen as misleading. The client carries the responsibility for the concrete use of the usage object and will only use it in accordance with the applicable laws, particularly from the area of competition law. The client will not permit any misleading or illegal use by third parties. DEKRA Certification GmbH is not liable for unauthorised use of the usage object.
- 5.10 The usage object may only be used during the period of validity given in the certificate and for as long as the certification is not suspended. If the validity period on the certificate ends before a recertification has taken place then the usage object may not be used before a new certificate has been issued.
- 5.11 In compliance with the certification requirements, DEKRA Certification GmbH is entitled to restrict, suspend, revoke and/or withdraw the right to use at any time if
- Prerequisites for the certificate issuance are not fulfilled (any longer), e.g. because incomplete or untrue information was provided in the certification process;
 - The client does not comply with the obligations associated with the certification, e.g. the information obligations regarding changes or performance obligations in the contract with DEKRA Certification GmbH, particularly payment obligations;
 - The contract with DEKRA Certification GmbH regarding certification ends;
 - A usage object is used contrary to usage conditions;
 - The necessary surveillance audit or another audit ordered by DEKRA Certification GmbH is not carried out fully or within the deadline;
 - The surveillance audit results in the certification requirements no longer being fulfilled;
 - Other grounds exist for the withdrawal of certification in accordance with these GCC or the contract.
- 5.12 If the certificate is withdrawn DEKRA Certification GmbH is entitled to terminate the contract for good cause. Other compensation and other claims remain unaffected.
- 5.13 Following the withdrawal of the certificate or the end of the certificate validity the client must stop all use of the usage object, particularly any advertisement that refers to the usage object or the service by DEKRA Certification GmbH upon which it is based and must return all certification documents demanded by DEKRA Certification GmbH. All certificates must be submitted to DEKRA Certification GmbH.
- 5.14 DEKRA Certification GmbH is not liable for damages caused to the client from the justified withdrawal of the certificate.

6. Use of the DEKRA Logo

- 6.1 If the DEKRA logo is shown on the issued certificate, DEKRA-seal or document then section 5 of these GCC applies. Otherwise the client is not entitled to use the name of DEKRA Certification GmbH, a company associated with DEKRA Certification GmbH or the DEKRA logo.
- 6.2 The client may not give the impression that it stands in any corporate or similar relationship with DEKRA Certification GmbH, a company associated with DEKRA Certification GmbH under public law or similar or that he could represent or obligate DEKRA Certification GmbH or a company associated with DEKRA Certification GmbH.

7. Use of the logo of an Accreditation Body/Designating Authority

The client is not entitled to use the logo of the Accreditation Body/Designating Authority except if such use is agreed separately in a contract.

8. Client obligations

Non-compliance with the obligation named in this section 8 can lead to performance becoming impossible and the auditor and/or the certification process needing to be discontinued. In the event of discontinuation of the audit section 3.2.3 applies. In the event of a serious breach of the named obligations DEKRA Certification GmbH is entitled to termination of the contract for good cause and withdrawal of the certificate and/or the DEKRA-seal on the basis of the more detailed provisions in section 5.11. Further compensation and other claims are unaffected.

General Certification Conditions (GCC) of DEKRA Certification GmbH for the business field of medical devices

8.1 Audit preparation

Before the audit the client will prepare all the documentation/information required for the audit and the certification in general or by DEKRA Certification GmbH beyond this and will make it available in good time.

8.2 Audit execution

8.2.1 The client undertakes to provide DEKRA Certification GmbH with all the required and relevant information, references and documents for the audits, general certification and otherwise truthfully, fully and on time. Documents must either be provided as copies or inspection must be facilitated. The client is obliged to provide at least representative samples of documents in accordance with further demands from DEKRA Certification GmbH. The client will pay any costs associated with the provision. The client must draw attention to all processes and circumstances that could be important in the execution of the order of his own account prior to the start of the audit. The client or suitable employees named by him must be available for the duration of the entire audit for enquiries.

8.2.2 The client is responsible for the maintenance of any relevant confidentiality or discretion obligations and data protection obligations when disclosing information to the auditor.

8.2.3 The client is obliged to provide the auditors with suitable rooms to carry out the audit on site.

8.3 Surveillance phase

After receiving the certificate the client undertakes to ensure that the prerequisites for the currently valid law, standard or system that are attested in the certificate are maintained for the entire period of the validity of the certificate and that these are inspected in audits in accordance with the detailed provisions in this contract.

The client is obliged to fulfil the certification requirements and to inform DEKRA Certification GmbH immediately and at all times of all modifications that influence the fulfilment of the requirements of granting the certificate or retaining the certificate.

9. Confidentiality and data protection

9.1 Confidentiality

9.1.1 'Confidential Information' describes all technical, financial, legal and fiscal information relating to design, inventions, marketing or other information (including data, diagrams and know-how) that is supplied to DEKRA Certification GmbH by the client in direct or indirect relation to the contract or that DEKRA Certification GmbH becomes aware of in another manner.

9.1.2 Information is not termed Confidential if

- It is already public knowledge at the time when DEKRA Certification GmbH becomes aware of it or if it became public knowledge after this without violation of this agreement;
- DEKRA Certification GmbH already knew it at the time when it became aware of it;
- DEKRA Certification GmbH received it from a third party before entering into this agreement or received it from a third party afterwards without violation of this agreement where the third party received the confidential information legally and did not violate a binding confidentiality obligation through its transfer;
- DEKRA Certification GmbH developed it without the use of Confidential Information.

9.1.3 DEKRA Certification GmbH will keep Confidential Information strictly confidential and not make it available to third parties by disclosure or otherwise and take suitable measures to protect the Confidential Information. DEKRA Certification GmbH may only use Confidential Information for the purpose of the preparation, estimation and execution of the contract and may not use it otherwise for its own benefit or for the benefit of third parties.

9.1.4 DEKRA Certification GmbH may disclose Confidential Information to associates with or without employee status, associated companies in accordance with §§ 15 et seq. of the German Code on Corporations and their staff with or without employee status and advisors who are obliged to maintain confidentiality where they are each subject to a relevant obligation to maintain confidentiality.

9.1.5 Confidentiality obligations are not valid if

- The client has agreed to the disclosure of Confidential Information to a third party for a concrete individual case in writing in advance;
- DEKRA Certification GmbH is obliged to disclose the Confidential Information by law, by court decision, the decision of an authority or other state body or based on the regulations of an Accreditation Body/Designating Authority.

9.1.6 DEKRA Certification GmbH is entitled to keep copies of the written documents transferred to DEKRA Certification GmbH for inspection or for execution of the order for its records. The client expressly states that he agrees that DEKRA Certification GmbH will provide the name/company name of the client, the usage object that the client may use (with identification method, e.g. ID number), validity of the usage object and other certificate-relevant information on the Internet for open access.

9.1.7 If DEKRA Certification GmbH provides Confidential Information to third parties in accordance with these GCC or other agreements with the client then DEKRA Certification GmbH will inform the client of this where possible and permitted.

9.1.8 In the event of a complaint relating to the client then DEKRA Certification GmbH, the client and the complainant will agree on the publication of any Confidential Information, especially the subject of the complaint and its resolution.

9.1.9 DEKRA Certification GmbH is entitled to retain information for the purpose of orderly records management and archiving, even after the end of the contract with the client.

9.2 Data protection

9.2.1 DEKRA Certification GmbH undertakes to observe the statutory data protection regulations.

9.2.2 DEKRA Certification GmbH is permitted to publish address data of the client and facts that are relevant for the certificate within the framework of the publication obligations by law or prescribed by the Accreditation Bodies/Designating Authorities. DEKRA Certification GmbH will also maintain a reference list with all certificate holders. The list will also be provided to third parties.

10. Prices

DEKRA Certification GmbH has calculated the prices agreed in the contract on the basis of the company information from the client. If circumstances within the client's company change or if the applicable laws, standards and regulations change then the contents of the audit that needs to be performed and of the certificate can also change. In this kind of case the agreed contract no longer fulfils its purpose. DEKRA Certification GmbH will therefore provide a new offer for services with new prices and any other necessary conditions. If the client accepts this

General Certification Conditions (GCC) of DEKRA Certification GmbH for the business field of medical devices

new offer then the agreed, modified contract is valid. If the client does not accept the new offer then DEKRA Certification GmbH is entitled to terminate the contract for good cause and, if a certificate was issued, to withdraw the certificate or DEKRA-seal in accordance with the detailed provisions in section 5.11.

11. Internal Audits, Second Party Audits and Multisite procedures

- 11.1 For internal audits and second party audits these GCC are valid with the exception of sections 4 (certification process structure) and 7 (use of the logo of an Accreditation Body/Designating Authority).
- 11.2 If a third party needs to be inspected / evaluated in the course of the second party audit and if DEKRA Certification GmbH has not agreed its own contract with the third party to be inspected/evaluated then the client will obligate this third party to observe these GCC as if the third party were the client himself.
- 11.3 In multisite procedures, the headquarters entity is obliged to ensure compliance of all multisite members with these GCC.

12. Subcontracting

The client agrees to the use of subcontractors by DEKRA Certification GmbH. However the certification decision is always made by DEKRA Certification GmbH itself.

13. Change of the certification requirements

- 13.1 DEKRA Certification GmbH has the right to change these GCC if and to the extent necessary to enable DEKRA Certification GmbH to perform its services in accordance with changed or amended Certification Requirements.
- 13.2 DEKRA Certification GmbH will inform the client about any amendments to the GCC within a reasonable period of at least three months. The client has the possibility to object to the change of the GCC within the prescribed period. If the client does not object within that period, the amended GCC shall be agreed and applied between the parties. In case the client objects both parties have the right to terminate the contract with a notice period of one month from the receipt of the objection at DEKRA Certification GmbH.

14. Invalidity of a regulation

In the event that one or several of the regulations in these certification conditions is invalid then the statutory regulation is agreed in its place. Where no statutory regulation exists the parties undertake to agree on a new, valid regulation that comes closest to the invalid regulation. The validity of the remaining regulations is unaffected.

Appendix: DEKRA-seal sample



Colour information of the DEKRA-seal: Green colour HKS 57K or CMYK 100/0/90/20