Special Certification Conditions (SCC) of DEKRA Certification GmbH for the business field of medical devices

A. Assessment of a quality management system in the field of medical devices according to Regulation (EU) 2017/745 and of in vitro diagnostic medical devices according to Regulation (EU) 2017/746

1. Duty of the client

The manufacturer shall establish a quality management system in accordance with Regulation (EU) 2017/745 (Medical Device Regulation) and/or (EU) 2017/746 (IVD Regulation), document and implement it and ensure its effectiveness throughout the life cycle of the devices concerned.

The client (hereafter referred to as “manufacturer”) will undertake to inform DEKRA Certification GmbH immediately in writing about serious incidents and field safety corrective actions in the meaning of the applied Regulation as soon as it becomes aware of them itself. Copies of the report forms of the initial report and the final reports that were sent to the competent authorities must be sent to DEKRA Certification GmbH. Copies of all decisions made by the competent authorities relating to the incidents need to be sent immediately and in full to DEKRA Certification GmbH.

In addition to reporting incidences, the manufacturer is obliged to immediately report in writing to DEKRA Certification GmbH any claims for compensation made by patients and users whether these lead to a court case or not that refer to products that are part of the certification of DEKRA Certification GmbH. Furthermore, DEKRA Certification GmbH is entitled to demand further information about possible product defects. The manufacturer is entitled to transfer anonymised information in order to protect confidentiality obligations.

Manufacturers of Class III medical devices or implantable products shall submit to DEKRA Certification GmbH the periodic safety update reports prepared in accordance with Article 86 of the Medical Device Regulation without being requested to do so. Manufacturers of IVD products of classes A sterile and B shall submit to DEKRA Certification GmbH, without being requested to do so, the report on post-marketing monitoring prepared in accordance with Article 80 of the IVD Regulation and updated as required.

Manufacturers of IVD products of classes C and D shall submit to DEKRA Certification GmbH the periodic safety update reports at least once a year prepared in accordance with Article 81 of the IVD Regulation without being requested to do so. In the case of Class D products this shall be done via the electronic system. If the electronic system referred to in Article 92 of the Medical Devices Regulation or Article 87 of the IVD Regulation is not yet operational, the safety reports must be submitted in a form specified by DEKRA Certification GmbH.

The manufacturer informs DEKRA Certification GmbH immediately in writing about planned significant changes. Changes are deemed significant if they affect:

- the quality management system or the product range covered by it
- the approved design of the product
- the approved type examination of a product
- (Medical Devices Regulation) the intended use of the product or the product information
- (Medical Devices Regulation) for substances contained in or used in the manufacture of a product and which are subject to the following processes:
  - Products of which a medicinal product is a constituent
  - products incorporating tissues or cells of human or animal origin as an integral part thereof
- (IVD Regulation) Substances contained in a product or used in the manufacture of a product and covered by the specific procedures:
  - Products which are companion diagnostics (Class C and D) and which are evaluated in a consultation procedure with the European Medicines Agency or a competent medicinal authority.
- and any other planned changes that may be relevant to the certification decision.

DEKRA Certification GmbH may make a new offer to the manufacturer to check whether the changed quality management system still meets the requirements of the regulation after the proposed changes. DEKRA Certification GmbH assesses the planned changes, informs the manufacturer of the decision and transmits the results of the evaluation. Approval of a significant change to the quality management system or the range of products covered by it is given in the form of a supplement to the EU quality management certificate. The manufacturer must provisionally allocate the medical devices covered by the applied-for certification under the applicable regulation into generic device groups and must notify DEKRA Certification GmbH about such allocation. DEKRA Certification GmbH will decide at its own discretion whether such allocation is correct or whether a different allocation needs to be made. The manufacturer must provide DEKRA Certification GmbH with all necessary information for such allocation and pledge its full cooperation.

The manufacturer will provide two copies of both the quality assurance system documentation required for the audit, as well as the technical documentation/ design dossier requested by DEKRA Certification GmbH and will do so in good time but at least six weeks before the desired audit date.

2. EU quality management system certificates

2.1 Issue of the certificates

For conformity assessment procedures, the following also applies:

A certificate is issued only where DEKRA Certification GmbH concludes that:

- proof of an implemented quality assurance system has been provided pursuant to the requirements of the regulation and,
- the technical documentation verified as part of the sampling plan meets the requirements of the Regulation.

2.2 Period of validity

The period of validity of the certificate is a maximum of 5 years, unless the certificate of DEKRA Certification GmbH provides for a shorter period of validity.

If the manufacturer wants a recertification from DEKRA Certification GmbH, the manufacturer will submit an application for recertification no later than eight months before the validity period of the certificate expires. The application for recertification shall be accompanied by a summary of the changes to and scientific findings on the product.

2.3 Restriction, suspension and withdrawal of the certificate

In addition to section 5.11 of the General Certification Conditions of DEKRA Certification GmbH for the business field of medical devices (GCC), the following applies:

DEKRA Certification GmbH has the right to suspend, limit or withdraw the certificate if the pertinent requirements for issuing the certificate are not or no longer met, or if the certificate should not have been issued − e.g. if the following situations arise:

- The device and/or the device category were mistakenly assigned as medical devices or IVD according to the applicable regulation.
- The medical device / IVD or the device category was assigned to a wrong class.
- The device and/or the device category is not or is no longer covered by the applicable regulation.
- The manufacturer refuses to allow or impedes the carrying out of an unannounced audit by DEKRA Certification GmbH.
- The manufacturer refrains from notifying a planned change or any other notification in accordance with Chapter 1.

DEKRA Certification GmbH is also entitled to withdraw the certificate without setting a deadline if the aforementioned reasons apply, this is prescribed by law and/or if DEKRA Certification GmbH has a duty toward the accreditation body and/or the designating authorities to do so.

2.4 Withdrawal of an application by the manufacturer

If the manufacturer withdraws their application before DEKRA Certification GmbH has issued a decision on the conformity assessment or if no certificate is issued, DEKRA Certification GmbH will inform the other Notified Bodies accordingly.

B. Device certification in the field of medical devices according to Regulation (EU) 2017/745 Annex IX Chapter II, Regulation (EU) 2017/746 Annex IX Chapter II and Regulation (EU) No. 722/2012

1. Duty of the manufacturer

The manufacturer must provide the product's technical documentation as well as, where applicable, one or, where necessary, several test samples for testing, free of charge and taking into account all export control law requirements. The technical documentation to be checked within the annual surveillance cycle is determined on the basis of the information entered by the manufacturer in the customer data sheet. In principle, the technical documentation of medical devices is reviewed on a representative basis for Class IIa and IIb products according to the Medical Devices Regulation and Classes B and C according to the IVD Regulation.

The manufacturer may not claim for compensation for damage to the test samples caused by the tests.

Test samples will be returned to the manufacturer or disposed of after testing is finished, at the discretion of DEKRA Certification GmbH.

1.1 Procedure for giving notification of changes

The manufacturer notifies DEKRA Certification GmbH about planned changes to the approved design dossier wherever the changes could affect conformity with the general safety and performance requirements or with the conditions prescribed for use of the device (see chapter 1 "Duty of the client"). DEKRA Certification GmbH may make the manufacturer a new offer for the assessment of the technical documentation. DEKRA Certification GmbH assesses the planned changes and decides whether these require a new conformity assessment or whether a supplement to the EU certificate for the assessment of the technical documentation could be issued. In the latter case, DEKRA Certification GmbH assesses the planned changes, informs the manufacturer of its decision and, if the changes have been approved, issues a supplement to the EU certificate on the assessment of the technical documentation.

Procedure in the case of devices incorporating a medicinal substance: Before changes are made to an auxiliary substance used in the medical device, particularly in connection with the manufacturing process, the manufacturer must inform DEKRA Certification GmbH of the changes. DEKRA Certification GmbH obtains an opinion from the consulted drug authority to confirm that the quality and safety of the auxiliary substance remains unchanged The consulted drug authority takes into account the information on the benefit of the use of the substance in the product as determined by DEKRA Certification GmbH to ensure that the changes do not adversely affect the benefit or risk previously established for the use of the substance in the product. The consulted drug authority shall send its opinion within 60 days of receipt of all the necessary documentation on the changes. DEKRA Certification GmbH will not issue a supplement to the EU certificate of assessment of the technical documentation if the scientific opinion of the consulted drug authority is negative. DEKRA Certification GmbH shall notify the consulted drug authority of its final decision.

Procedure in the case of products incorporating animal tissue: The manufacturer of products according to regulation (EU) No. 722/2012 submits the collected and evaluated information regarding changes with regard (i) to the animal tissue or derivatives used for the device or with regard (ii) to the risk of transmitting animal spongiform encephalopathy (TSE) agents in relation to the device.

Special procedure under the Regulation (EU) 2017/746:

Where changes to products may affect compliance with the Common Specifications (CS) or other solutions adopted by the manufacturer that have been approved with the EU Technical Documentation Assessment Certificate, the EU reference laboratory and, where appropriate, the panel of experts involved in the original consultation shall be involved in the re-assessment and subcontracted.

In addition, in the case of modifications to companion diagnostics which affect the performance and/or intended use and/or suitability of the device in relation to the medicinal product concerned, an assessment shall be made as to whether a new conformity assessment is required. If this is the case, the medicinal product authority consulted shall be involved in the re-assessment and subcontracted.

1.2 Batch testing concerning IVD products of class D according to Regulation (EU) 2017/746

For products in Class D, the manufacturer shall carry out tests on each batch of products manufactured. After completion of the controls and tests, the manufacturer shall immediately send the relevant test reports to DEKRA Certification GmbH.

In addition, the manufacturer shall provide DEKRA Certification GmbH with samples of the manufactured products or product batches in accordance with previously agreed conditions and modalities; this includes that the Notified Body or the manufacturer shall send samples of the manufactured products or product batches to an EU reference laboratory designated in accordance with Article 100 so that the latter can carry out appropriate laboratory tests.

The EU reference laboratory shall inform DEKRA Certification GmbH of its findings. Only if the manufacturer's controls and the laboratory tests of the EU reference laboratory lie within the release specifications, DEKRA Certification GmbH grants the manufacturer permission to place the manufactured product on the market.

The manufacturer may place the products on the market unless the notified body notifies him of another decision within the agreed time limit but no later than 30 days after receipt of the samples, in particular regarding the conditions for the validity of the certificate issued.

The manufacturer may place the products on the market no later than 30 days after receipt of the sample, unless the notified body notifies him of another decision within the agreed time limit, in particular regarding the conditions for the validity of the certificate issued.

2. EU technical documentation assessment certificate

2.1 Period of validity / scope

The scope covers those products listed on the certificate and on the annex to the certificate.

The period of validity of the certification totals maximal 5 years unless another period was defined in the certificate issued by DEKRA Certification GmbH.

For a certificate on the assessment of the technical documentation to be valid in accordance with Medical Device and In-Vitro Diagnostic Devices regulation, a valid certificate issued by DEKRA Certification GmbH pursuant to section A point 2 is required.

If the manufacturer wants a recertification from DEKRA Certification GmbH, the manufacturer will submit a corresponding application no later than eight months before the validity period of the certificate expires.

2.2 Restriction, suspension and withdrawal of the certificate

In addition to section 5.11 of the General Certification Conditions of DEKRA Certification GmbH for the business field of medical devices (GCC), the following applies:

DEKRA Certification GmbH has the right to suspend, limit or withdraw the certificate if the pertinent requirements for issuing the certificate have not or are no longer met, or if the certificate should not have been issued − e.g. if the following situations arise:

- The device and/or the device category were mistakenly assigned as medical devices or IVD according to the regulation.
- The medical device / IVD or the medical device category was assigned to a wrong class.
- The device and/or the device category is not or is no longer covered by the regulation.
- The manufacturer refuses to allow or impedes the carrying out of an unannounced audit by DEKRA Certification GmbH.
- In the case of a EU technical documentation assessment certificate if no valid EU quality management system certificates issued by DEKRA Certification GmbH is available.
- The manufacturer refrains from notifying a planned change or any other notification in accordance with Chapter 1.

DEKRA Certification GmbH is also entitled to withdraw the certificate without setting a deadline if the aforementioned reasons apply, this is prescribed by law and/or if DEKRA Certification GmbH has a duty toward the accreditation body and/or the designating authorities to do so.

C. Unannounced audits

1. Definitions

"Unannounced audits" refer to such audits carried out by DEKRA Certification GmbH in accordance with the certification requirements without prior appointment with the manufacturer or prior notice to the manufacturer or third parties.

„**Subcontractor**" is a supplier of the manufacturer.

2. Process

2.1 Objective

Unannounced audits serve to verify day-to-day compliance with the legal obligations of the manufacturer. They are conducted in addition to other audits.

2.2 Implementation site

Unannounced audits are conducted at the premises of the manufacturer and/or a subcontractor.

DEKRA Certification GmbH is particularly entitled to go to the business premises of a subcontractor to ensure more efficient control in place of or in addition to the unannounced audit at the premises of the manufacturer. An unannounced audit at the premises of a subcontractor is used in particular to ensure efficient control if the design, manufacture, testing, or other important operations are primarily carried out here.

2.3 Frequency

An unannounced audit can be carried out at least once every five years; DEKRA Certification GmbH can increase the frequency at its own discretion and in accordance with the certification requirements if the products pose a substantial risk, if the products of the relevant type frequently fail to conform, if certain information indicates that either the products or the manufacturer do not conform or there is another reason to doubt that the certificate can be maintained.

2.4 Implementation

2.4.1 Duration

Unannounced audits last no less than one day. The duration depends on the number of the products/product groups to be tested and the selected conformity evaluation process.

2.4.2 Audit Team

Unannounced audits are executed by an audit team consisting of at least two persons.

2.4.3 Device sample and -test

DEKRA Certification GmbH is entitled to investigate a suitable, recently taken sample, preferably a device from the ongoing production process, in terms of its conformity with technical documentation and legal requirements.

When controlling device conformity, DEKRA Certification GmbH is entitled to also check the traceability of all critical components and materials as well as the manufacturer's traceability system.

The control process includes checking the documents and, if this is necessary to determine conformity, a test of the device. The test is carried out in accordance with the test procedure that the manufacturer specified in the technical documentation. The test can also be carried out by the manufacturer or subcontractor subject to observation by DEKRA Certification GmbH, if and to the extent that DEKRA Certification GmbH so orders.

The manufacturer must hand over all relevant technical documentation including previous test protocols and results to DEKRA Certification GmbH to prepare the test.

If it is not possible to take a sample at the premises of the manufacturer or of the subcontractor, DEKRA Certification GmbH is entitled, against remuneration for all costs incurred by it, to take samples from the market, if necessary, with support from the competent authorities, or to perform testing on a device installed at a customer location.

To prepare the test, the manufacturer must hand over all relevant technical documentation including final batch testing reports and previous test protocols and results to DEKRA Certification GmbH.

2.4.4 Quality assurance system

Insofar as DEKRA Certification GmbH has been commissioned to evaluate the quality assurance system, DEKRA Certification GmbH is entitled to verify whether manufacturing activity ongoing at the time of the unannounced audit is in line with the manufacturer's documentation relevant for the manufacturing activity and that both the activity and documentation are in conformity with legal requirements. In addition, DEKRA Certification GmbH is entitled to check in more detail at least two critical processes such as design control, establishment of material specifications, purchasing and control of incoming material or components, assembling, sterilisation, batch-release, packaging, or device quality control.

2.4.5 Duties of the manufacturer

The manufacturer must cooperate in full with unannounced audits to allow DEKRA Certification GmbH to conduct the audit in accordance with certification requirements. During the unannounced audit, the manufacturer will provide immediately the documents/information generally required for the audit and that for the certification, and any further documentation/information demanded by DEKRA Certification GmbH, and will report all other information relevant for the certification or audit at its own initiative.

The manufacturer ensures that DEKRA Certification GmbH can also conduct an unannounced audit at the premises of the subcontractor and likewise the corresponding contractual obligation of subcontractors. For this purpose, the manufacturer will oblige all its subcontractors to grant DEKRA Certification GmbH access for an unannounced audit in accordance with this contract and the certification requirements and to cooperate in full. If a visa must be issued or another measure must be implemented to conduct the unannounced audit (e.g. to ensure the safety of the auditors), the manufacturer will do everything necessary to ensure such a visa can be issued or such other measures can be implemented.

The client must accept responsibility for the conduct of the subcontractor in connection with the unannounced audit.

In addition, the manufacturer will notify DEKRA Certification GmbH at least three months in advance and in writing of such periods in which an unannounced audit is not possible (e.g. because products to which the certification relates are not manufactured at this time; company holidays, etc.). Insofar DEKRA Certification GmbH has determined the form and content of the notification, this requirement must be followed.

2.4.6 Remuneration

The manufacturer must pay for the unannounced audit in accordance with the applicable contract and agreed prices. This applies regardless of where the unannounced audit is conducted (e.g. at the premises of a subcontractor). Expenses must be reimbursed.

If an unannounced audit does not take place and the reason for this falls within the sphere of influence of the manufacturer or subcontractor (this also includes a labour dispute or strike, or a late or missed notification under Section 2.4.5), the manufacturer will reimburse DEKRA Certification GmbH the additional expenses incurred by DEKRA Certification GmbH from the preparation and/or unsuccessful provision of audit services as well as for postponing the unannounced audit. The same applies if the manufacturer or subcontractor cancels an unannounced audit that has started or if DEKRA Certification GmbH cancels an unannounced audit that has started and this cancellation falls within the sphere of influence of the manufacturer or subcontractor.

2.4.7 Termination

If the manufacturer or subcontractor does not cooperate with conducting the unannounced audit, and an unannounced audit can therefore not take place or not take place in a timely manner in accordance with the certification requirements, DEKRA Certification GmbH has the right to terminate the contract for cause. Further compensation claims and other claims of DEKRA Certification GmbH remain unaffected. DEKRA Certification GmbH is also entitled, if a certificate and/or a DEKRA Seal was issued, to suspend or withdraw the certificate or DEKRA seal in accordance with the more detailed conditions set out in section 5.11 of the General Certification Conditions of DEKRA Certification GmbH for the business field of medical devices (GCC).

D. Audits ordered at the premises of subcontractors

1. Definitions

"**Subcontractor audits**" are audits that are conducted by DEKRA Certification GmbH at the premises of a subcontractor.

„**Subcontractor**" is a supplier of the manufacturer.

2. Process

2.1 Objective

To ensure effective control, DEKRA Certification GmbH is entitled to conduct audits at the premises of subcontractors. To this end, DEKRA Certification GmbH must have access to all sites where the products or its essential components are produced.

2.2 Implementation site

Subcontractor audits are carried out at the relevant production sites of the subcontractors.

2.3 Frequency and content

Subcontractor audits are ordered at the discretion of DEKRA Certification GmbH if and to the extent that they are necessary to ensure effective control in addition to other audits at the premises of the manufacturer.

The contents of the subcontractor audits is set out in a separate offer.

2.4 Duties of the manufacturer

The manufacturer must cooperate in full with subcontractor audits to allow DEKRA Certification GmbH to conduct the audit in accordance with certification requirements.

Before and during the subcontractor audit, the manufacturer will provide the documents/information generally required for the audit and that for the certification, as well as any further documentation/information demanded by DEKRA Certification GmbH and will report on its own initiative or otherwise ensure notification of all other information relevant for the certification or audit.

The manufacturer will ensure that DEKRA Certification GmbH can also conduct a subcontractor audit at the premises of the subcontractor and will establish the corresponding contractual obligation of subcontractors. For this purpose, the manufacturer will oblige all its subcontractors to grant DEKRA Certification GmbH access for a subcontractor audit in accordance with this contract and the certification requirements and to cooperate in full. If a visa must be issued or another measure must be implemented to conduct a subcontractor audit (e.g. to ensure the safety of the auditors), the manufacturer will do everything necessary to ensure such a visa can be issued or such other measures can be implemented.

The manufacturer is responsible for the conduct of the subcontractor in connection with the subcontractor audit.

2.5 Remuneration

The manufacturer must pay for the subcontractor audit in accordance with the applicable contract and the agreed prices. Expenses must be reimbursed.

If a subcontractor audit does not take place and the reason for this falls within the sphere of influence of the manufacturer or subcontractor (this also includes a labour dispute or strike), the manufacturer will reimburse DEKRA Certification GmbH the additional expenses incurred by DEKRA Certification GmbH from the preparation and/or unsuccessful provision of audit services as well as for postponing the subcontractor audit. The same applies if the manufacturer or subcontractor cancels a subcontractor audit that has started or if DEKRA Certification GmbH cancels a subcontractor audit that has started and this cancellation falls within the sphere of influence of the manufacturer or subcontractor.

2.6 Termination

If the client or subcontractor does not cooperate with conducting subcontractor audits, and an subcontractor audit can therefore not take place or not take place in a timely manner in accordance with the certification requirements, DEKRA Certification GmbH has the right to terminate the contract for cause. Further compensation claims and other claims of DEKRA Certification remain unaffected. DEKRA Certification GmbH is also entitled, if a certificate and/or a DEKRA seal was issued, to suspend or withdraw the certificate or DEKRA seal in accordance with the more detailed conditions set out in section 5.11 of the General Certification Conditions of DEKRA Certification GmbH for the business field of medical devices (GCC).

2.7 Note to the manufacturer

The manufacturer is explicitly made aware that the manufacturer

a) has to fulfil its obligations itself regardless of any partial or total outsourcing of the production via subcontractors or suppliers;

b) does not fulfil its obligation to have at its disposal the full technical documentation and/or of a quality system by referring to the technical documentation of a subcontractor or supplier and/or to their quality system;

c) must control the quality of services provided and components supplied as well as the quality of production, regardless of the length of the contractual chain between the manufacturer and the subcontractor.

E. Distribution of responsibility; Liability to third parties

1. Responsibilities

The manufacturer carries sole responsibility to ensure that both the manufacturer and the medical devices manufactured or distributed by the manufacturer comply fully with all legal requirements. The activity of DEKRA Certification GmbH serves exclusively to allow the manufacturer to prove the marketability of medical devices to the relevant authorities.

DEKRA Certification GmbH is not liable to third parties in principle, e.g. to patients who use or utilise the manufacturer's products. DEKRA Certification GmbH only provides its services to the manufacturer. Third parties are only included in the scope of protection/performance if this is expressly agreed in a written contract.

If the contractual performance of third parties is included in the scope of protection, then the manufacturer must inform these third parties of the contractually agreed limitation of liability and of the exact scope of performance before use of the service.

2. Claim by a third party

The parties clarify that in their relationship to third parties, particularly patients, only the manufacturer is responsible for defects in the medical device or breaches of duty on the part of the manufacturer. There is no overall debt for any compensation claims by patients between the manufacturer and DEKRA Certification GmbH.

If claims are made against DEKRA Certification GmbH for compensation by third parties for (alleged) defects in the medical device or breaches of duty by the manufacturer, then the manufacturer will fully indemnify DEKRA Certification GmbH at the first request and will refund DEKRA Certification GmbH reasonable costs for legal defence.

If claims are made against DEKRA Certification GmbH by third parties because of a defective medical device or a breach of duty towards this third party by the manufacturer then the manufacturer already assigns future claims against its liability insurance, which is valid in such cases, to DEKRA Certification GmbH.

If the claims are made by third parties at the same time against the manufacturer for defects in the medical device or a breach of duty, then the manufacturer undertakes to do its best to protect DEKRA Certification GmbH from further claims, in particular the manufacturer will pay the third party compensation for recognised claims.