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

A. Certification of quality assurance systems in the field of medical devices according to Directives 93/42/EEC

1. Duty of the client

The client (hereafter referred to as “manufacturer”) will undertake to inform DEKRA Certification GmbH about incidents in the meaning of the directives 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 to DEKRA Certification GmbH.

Beyond reporting incidences, the manufacturer is obliged to immediately report to DEKRA Certification GmbH any claims for compensation made by patients and users in and out of court 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.

The manufacturer will inform DEKRA Certification GmbH about significant planned changes to the quality assurance system or to the range of devices or device series covered by this. DEKRA Certification GmbH will, if necessary, provide the manufacturer with a new offer to test whether the quality assurance system will still meet the requirements of Directives 93/42/EEC after the changes are implemented.

The manufacturer must provisionally allocate the medical devices covered by the applied-for certification under Directives 93/42/EEC into subcategories and, for devices in Class IIb under Directive 93/42/EEC, also into generic device groups and must notify DEKRA Certification GmbH about such allocation. DEKRA Certification GmbH will decide in 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. 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 directive and,
- the technical documentation verified as part of the sampling plan meets the requirements of the Directive.

2.2 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. A report must be submitted with the application for recertification that contains details of whether and to what extent the evaluation criteria for the conformity assessment have changed since the certificate was issued or extended.

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 according to the Directive 93/42/EEC.
- The medical device 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 Directive 93/42/EEC.
- The manufacturer refuses to allow or impedes the carrying out of an unannounced audit by DEKRA Certification GmbH.
- The manufacturer fails to immediately report compensation claims by patients or users that refer to products that are part of the certification of DEKRA Certification GmbH.

DEKRA Certification GmbH is also entitled to withdraw the certificate without setting a deadline if 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.

B. Device certification in the field of medical devices according to Directives 93/42/EEC and Regulation (EU) No. 722/2012

1. Duty of the manufacturer

The manufacturer must provide the technical documentation and/or design documentation on the product 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 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 essential requirements of the Directive 93/42/EEC or with the conditions prescribed for use of the device. DEKRA Certification GmbH will, if necessary, make the manufacturer a new offer to assess whether the modified design still meets the essential requirements of Directive 93/42/EEC following proposed changes.

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.

2. Certificates

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 to be valid in accordance with Directive 93/42/EEC Annex II.4, a valid certificate issued by DEKRA Certification GmbH pursuant to Directive 93/42/EEC Annex II excluding section (4) is required.

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. A report must be submitted with the application for recertification that contains details of whether and to what extent the evaluation criteria for the conformity assessment have changed since the certificate was issued or extended.

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 according to the Directive 93/42/EEC.
- The medical device 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 Directive 93/42/EEC.
- The manufacturer refuses to allow or impedes the carrying out of an unannounced audit by DEKRA Certification GmbH.
- In the case of a certificate pursuant to Directive 93/42/EEC Annex II.4 if no valid certificate issued by DEKRA Certification GmbH is available pursuant to Directive 93/42/EEC Annex II excluding section (4).

DEKRA Certification GmbH is also entitled to withdraw the certificate without setting a deadline if 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 „critical subcontractor" or a "crucial supplier".

"Critical subcontractor" is the subcontractor of the manufacturer or the subcontractor of a subcontractor in charge of processes that are essential for ensuring compliance with legal requirements.

"Crucial supplier" is a supplier of crucial components or of the entire devices irrespective of whether it is the supplier of the manufacturer or the supplier of a supplier or a subcontractor 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. DEKRA Certification GmbH is entitled but not obliged to carry out such unannounced 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 three 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 auditteam 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.

Insofar as DEKRA Certification GmbH was commissioned to check the design dossier pursuant to Directive 93/42/EEC Annex II.4, DEKRA Certification GmbH is also entitled to take device samples belonging to at least three different device types and, where the manufacturer produces more than 99 device types, devices belonging to at least every hundredth type at the end of the production chain or in the warehouse of the manufacturer with a view to controlling the conformity of device types. Variants with a technical difference that could affect the safety or performance of the device are to be regarded as a separate device type. Variants with differences in size are not to be regarded as separate types insofar as the size is not associated with any particular risks. These samples are examined by DEKRA Certification GmbH at its own facilities, the business premises of the manufacturer or its subcontractor, or in external laboratories.

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 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 will ensure that DEKRA Certification GmbH can also conduct an unannounced 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 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 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 observed.

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 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 "critical subcontractor" or "crucial supplier".

"**Critical subcontractor**" is the subcontractor of the manufacturer or the subcontractor of a subcontractor that is responsible for manufacturing processes that are relevant for ensuring compliance with legal requirements**.**

"**Crucial supplier**" is a supplier of essential device components or of the entire device, regardless of whether this supplier is the supplier of the manufacturer, or a supplier of a supplier or of the manufacturer's subcontractor.

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 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 manufacturers

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) should integrate the quality assurance system of the subcontractors in its quality assurance system;

d) 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 fulfil the 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.