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

A. Surveillance of the applicable requirements for devices placed on the market under Regulation (EU) 2017/745 Article 120 (3)

1. Duty of the client

The client (hereinafter referred to as "manufacturer") shall establish a quality management system in accordance with regulation (EU) 2017/745 (MDR), which it shall document and implement and ensure its effectiveness throughout the life cycle of the devices concerned.

The manufacturer authorises DEKRA Certification GmbH to carry out all necessary activities for surveillance. These include regular surveillance audits, post-audits, extraordinary audits, unannounced audits, reviews of the technical documentation, evaluation of changes, product tests as well as further audits if required. DEKRA Certification GmbH shall determine the necessary surveillance activities at its own discretion.

The manufacturer undertakes that the devices which are placed on the market after 26 May 2021 in accordance with the transitional provisions of MDR Article 120 (3)

- are covered by a valid certificate issued by DEKRA Certification GmbH in accordance with Directive 93/42/EEC Annex II without (4), Annex V or Annex VI on the day of placing on the market,
- if they belong to Class III according to Directive 93/42/EEC, they are additionally covered by a valid design examination certificate issued by DEKRA Certification GmbH according to Directive 93/42/EEC Annex II.4,
- continue to comply with the provisions of Directive 93/42/EEC,
- no significant change in design and intended use, and no changes relevant to certification apply,
- the technical documentation for the product is maintained and kept up to date,
- meet the requirements of regulation (EU) 2017/745 on post-market surveillance, vigilance, registration of economic operators and products.

The manufacturer must at all times be able to state in writing, beyond any doubt, which devices were placed on the market after 26 May 2021 in accordance with the transitional provisions.

The manufacturer undertakes to inform DEKRA Certification GmbH in writing and without delay of serious incidents and field safety corrective actions according to the applied regulation as soon as he himself becomes aware of them. Copies of the official notification forms of the initial reports and the final reports sent to the competent authorities shall be sent to DEKRA Certification GmbH. All copies of decisions made by the competent authorities on incidents must be sent to DEKRA Certification GmbH immediately and in full.

In addition to the notification of incidents, the manufacturer is obliged to immediately notify DEKRA Certification GmbH in writing of any claims for damages asserted by patients and users both in and out of court that relate to devices that are part of the certification of DEKRA Certification GmbH. In addition, DEKRA Certification GmbH shall be entitled to request further information about possible defects of devices. In order to comply with confidentiality obligations, the manufacturer shall be entitled to transmit anonymised information.

The manufacturer of Class III medical devices or of implantable devices shall submit to DEKRA Certification GmbH the safety reports drawn up in accordance with the MDR Article 86 without being requested to do so.

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.

The manufacturer shall continue to inform DEKRA Certification GmbH of any planned significant changes to the quality management system or the products covered by it. DEKRA Certification GmbH assesses the planned changes and decides whether the affected products still comply with EU Directive 93/42/EEC or whether a new conformity assessment is required in accordance with regulation (EU) 2017/745. If necessary, DEKRA Certification GmbH makes the manufacturer a new offer for the assessment of the technical documentation.

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 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 Directive 93/42/EEC.
- The medical device or the device category was assigned to a wrong class.
- The manufacturer refuses or impedes the carrying out of an announced or unannounced audit by DEKRA Certification GmbH.
- The manufacturer refrains from notifying a planned change or any other notification in accordance with Chapter 1.
- The requirements specified in Chapter 1 for the applicability of the transitional provisions of MDR Article 120 (3) after 26 May 2021 are partially or completely not fulfilled or have subsequently ceased to apply.

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 the competent authority or designating authority oblige DEKRA Certification to do so.

B. 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

DEKRA Certification GmbH may determine the frequency of unannounced audits at its own discretion.

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 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 other measures can be implemented.

The manufacturer shall be responsible for the subcontractor's behaviour with regard to 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).

C. 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 shall be responsible for the subcontractor's behaviour with regard to the unannounced 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 a 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).

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.

D. Distribution of responsibility; Liability towards 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 of the medical device or breaches of duty by 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 of 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 by the manufacturer towards this third party then the manufacturer already assigns future claims against its liability insurance, which is valid in such cases, to DEKRA Certification GmbH.

If at the same time claims are made by third parties against the manufacturer for defects of 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.