



### General Purchase Conditions Healthcare (GPC)

General Purchase Conditions Healthcare of the Dutch Hospital Association (NVZ), Association of the Care for People with Disabilities in the Netherlands (VGN), ActiZ, organization of healthcare entrepreneurs, Dutch Mental Health Care (GGZ), Dutch Procurement Association (Nevi), Intrakoop, the healthcare purchase cooperative, Purchase Alliance Hospitals (IAZ), Santeon, Purchase Cooperation Friesian Hospitals (IFZ), mProve, and Zorgservice XL. These general purchase conditions can be declared applicable to agreements to be concluded between institutions affiliated with the aforementioned trade associations and suppliers. These "Algemene Inkoopvoorwaarden Gezondheidszorg (AIVG 2022)" have been deposited with the District Court of The Hague, dated November 14, 2022 under deposit number 2022/33.

**Intrakoop**



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## Article 1 Definitions

Within these General Purchase Conditions Healthcare 2022, capitalized terms have the meanings attributed to them in this article 1 and in the General Purchase Conditions Healthcare (GPC).

**Call-off contract** An Agreement under which a pre-agreed amount can be ordered (called off) by Client with Supplier at their discretion, at pre-agreed prices and conditions, according to their needs.

**GPC:** these General Purchase Conditions Healthcare 2022.

**Loan agreement:** An Agreement under which Supplier provides a product to Client without charge, provided that Client returns the Product after use or after the agreed usage period has expired.

**Circularity:** closing loops wherein products and materials are reused and resources maintain their value for as long as possible.

**Consignment:** A Written agreement for a period under which a Product is kept in the care of Client by Supplier at no cost, with ownership transferring from Supplier to Client upon use.

**Services:** Non-tangible service/work to be performed as part of the performance.

**Documentation:** Technical documentation, user manuals, warranty certificates, specifications, inspection regulations, instructions, and safety sheets.

**Deficiency:** A malfunction or failure of the Performance to meet the agreed specifications, or improper functioning of the Performance, or otherwise not being suitable for normal use of the Performance by Client.

**Average Service Life:** The service life of a product as expected by Client based on, for example, a Life Time table or the Documentation, website, or communication of Supplier with Client.

**Raw Material Passport:** A document that provides insight into the raw materials and materials a Product is made of, the extent to which recycled materials have been used, and the extent to which the Product is recyclable after its service life.

**Auxiliary materials:** supporting tools, tools, drawings, models, software, and other aids (including but not limited to e-learning modules) for the purpose of the Product, not being Medical Devices.

**Purchasing Association:** the collaboration between a number of Clients aimed at jointly purchasing Performance for more favourable conditions.

**Supplier:** the counterparty of Client.

**Medical Devices:** Products to which the Medical Devices Act and lower regulations based on this Act apply.

**Quotation:** the Written offer to deliver a certain Performance subject to certain conditions.

**Parts:** components of a Product.

**Client:** one or more (healthcare) institutions who use this GPC as a purchasing entity.

**Order:** the order of Client to Supplier to deliver a Performance to Client based on certain conditions.

**Agreement:** every agreement entered into between Client and Supplier concerning the delivery by Supplier to Client of a Performance, as well as every amendment or addition thereto including all (legal) acts required for entering into or performing the Agreement, as stipulated in article 217 of Book 6 of the Dutch Civil Code.

**Parties:** Client and Supplier and also each separately.

**Performance:** the agreed Products, rights of use and other property rights to be supplied and delivered by Supplier to Client, the Services to be rendered by Supplier for the benefit of Client, as well as the creation and delivery of a material work and the Works to be provided by Supplier for the benefit of Client.

**Products:** goods to be provided as part of the Performance.

**Trial shipment/placement:** a form of acquisition for the purpose of temporarily deploying the Product in patient care and/or the organisation for assessment of this Product.

**Recall:** the recall and removal from Client's site(s) of Products with a quality defect or risk of use identified by Supplier or Client. A Recall will occur with respect to a detected deviation in quality, safety, functioning and processing of a Product that leaves it short of the safety and/or functioning that can reasonably be expected.

**Spare parts:** a Product's replacement components that are not yet built in or connected.

**Safety Notification:** A notification by Supplier, warning that in some situations the safety or quality of a method or Product can fall short. By taking the measures prescribed (in the Safety Notification), the reported safety or quality issue can be controlled.

**Associated Agreement:** an Agreement that would not have come into existence without the Agreement.

**Writing/Written:** formal communication between Parties in writing, including on paper and by electronic message.

**Works:** all construction, civil engineering and infrastructure work including alteration and maintenance work beyond the mere maintenance of the Work.

**Display shipment / placement:** a type of procurement aimed at evaluating the Product without deploying it in patient care and/or the organisation.

## Article 2 Applicability

- 2.1 These General Purchase Conditions Healthcare (GPC) govern all requests, Quotations, offers, (purchase) Orders, order confirmations, Agreements and all other legal acts between Client and Supplier.
- 2.2 The applicability of any general or specific conditions or stipulations of Supplier, under whatever name, is expressly rejected.
- 2.3 Should in the court's opinion any provision of the GPC be inapplicable or invalid, only the relevant provision will be considered unwritten, but the GPC will otherwise remain in full force and effect. The parties will consult to replace the relevant inapplicable or invalid provision with a new provision, which will respect as much as possible the purpose and purport of the earlier provision.
- 2.4 In case of conflict between the provisions of the GPC and the provisions of the Agreement, the provisions of the Agreement will prevail.
- 2.5 Deviations from these GPC can only be agreed in Writing.
- 2.6 In case of differences between the meaning of the Dutch text of this GPC and that of its translations into other languages, the Dutch text will prevail.

## Article 3 Establishing the Agreement

- 3.1 The request for a Quotation is deemed an invitation to produce an offer and does not bind Client. A request for quotation from Client will be followed by a Supplier's Quotation. The costs of producing this Quotation will be for Supplier's account and the Quotation will be regarded as an offer. Quotations are unconditional and irrevocable within the validity period of the Quotation specified by Supplier.
- 3.2 Client will be entitled to revoke the order or cancel the Order at any time, unless Supplier proves that it has commenced performance of the Agreement. In that case, Client will reimburse Supplier of costs incurred by the latter insofar these costs are demonstrable and reasonable. These costs may be demonstrated by means of invoices, issued Orders or demonstrably performed activities.
- 3.3 If an Order results from a Quotation issued by Supplier, then the Agreement will come into force at the moment the Order is submitted by Client and deemed to have been received by Supplier. Orders not in Writing are not binding on Client unless Client ratifies such orders in Writing.

- 3.4 If an Order is placed by Client without an offer by Supplier preceding it, the Agreement will come into force when Supplier accepts this Order in Writing, provided that this acceptance occurs within 14 calendar days after placement of that Order. In the absence of a Written acceptance by Supplier, the Agreement is formed when the Performance is delivered in accordance with the Order and the Performance is accepted by Client without prejudice to the provisions of clause 7.9, provided that such delivery is made within 21 calendar days from the date of the Order.
- 3.5 For Call-off orders, the Agreement for (partial) delivery comes into force at the moment that the Written order for delivery is sent by Client, unless otherwise agreed.
- 3.6 If Auxiliary Materials and Documentation made available or approved by Supplier are used in the performance of the Agreement, they will form part of the Agreement.
- 3.7 Supplier is deemed to be sufficiently aware of Client's objectives pertaining to the Agreement and Client's organisation.

#### Article 4 Modifications

- 4.1 Client is authorized, in consultation with Supplier and within a reasonable timeframe, to change the scope and quality of the Performances delivered, unless these changes bear such consequences that Supplier cannot reasonably be expected to cooperate without good cause. Supplier will then inform Client thereof In Writing as soon as possible, but at the latest within eight calendar days after notification of the change. If possible, Supplier will then propose new conditions, which can be reasonably accepted or rejected by Client.
- 4.2 Amendments will not take effect until they have been recorded in Writing and signed by authorized representatives of the Parties.

#### Article 5 Prices

- 5.1 The agreed prices are fixed for the duration of the Agreement and therefore cannot be subject to revision, with the exception of an annual indexation provided that this is set out in Writing at the start of the Agreement.
- 5.2 Prices are denominated in Euro (€), excluding sales tax and are based on the delivery condition "delivered duty paid" (D.D.P.) pursuant to the Incoterms® 2020 on the agreed place of delivery. All costs are included in the price, unless expressly stated otherwise in the Agreement. The Parties will endeavour to have as many Products as possible delivered in the same order to reduce Supplier's freight costs and environmental impact.
- 5.3 Supplier is required to state the applicable VAT rate on Quotations and invoices, among others.
- 5.4 In case of changing VAT rates and/or changed classification (high, low or 0%), Supplier will adjust the rate.

#### Article 6 Purchasing Associations

If Client participates in a Purchasing Association and can thereby gain an advantage over what was offered by Supplier directly to Client, Client has the right to take advantage of the offer to the Purchasing Association and amend ongoing Agreements in favour of Client reasonably and in consultation with Supplier.

## Article 7 Delivery

- 7.1 Delivery of a Product will take place D.D.P. in accordance with Incoterms®2020 at the agreed delivery address(es) as specified in the Order, unless expressly deviated from in the Agreement.
- 7.2 The agreed delivery time and delivery period, as well as the latest date by which the Performance must be performed, are deadlines. In the event of late delivery, Supplier is in default without further notice of default. If Supplier expects that the delivery cannot be made in time in accordance with the agreements, it will immediately notify Client's purchasing department thereof In Writing, specifying the circumstances giving rise to it, and Supplier will immediately make a proposal for taking interim measures.
- The interim measures will be equivalent to the agreed Performance and will not involve any additional costs for Client. An interim measure will only substitute the concerned Performance pending written approval of Client. Client may refuse the interim measure proposed by Supplier and arrange one by himself, provided Client has serious and reasonable arguments to do this. In that case, Client may require that a Performance of another Supplier be temporarily engaged as an interim measure - the costs for the relevant interim measure being for Supplier's account.
- If there are any risks in the supply chain in terms of availability, Supplier will proactively make these transparent.
- 7.3 In so far as the Performance involves the delivery of Products, a packing list must be present. This packing list will be clearly attached on the outside of the transport packaging. The packing list must specify the order number(s) of Client, and also the item number(s), amount(s), item description(s) and if applicable serial numbers.
- 7.4 For successive deliveries of Products, Supplier will endeavour for the last delivery to have an expiry date that lapses later than, or at the least on the same date as the prior delivery of these products.
- 7.5 If, in the opinion of Client, the shelf life of the Products to be delivered is too close to the expiry date, Client is authorized to refuse these Products. A rejection of the Product pursuant to this paragraph will not entitle Supplier to a reimbursement of any damage.
- 7.6 Supplier and Client may agree to supply Products with a shorter shelf life than previously agreed. These Products can be exchanged free of charge if the Products are not used within the expiry date, unless otherwise agreed. Client will endeavour to first use Products with the shortest shelf life.
- 7.7 Delivery includes the provision of all related Auxiliary Materials and Documentation. If deemed necessary for proper use of the Product, Supplier will provide training for Client's staff entrusted with the use of the Product, whereby the Parties will agree in advance on the costs or any fees for such training.
- 7.8 If Client requests Supplier to postpone the delivery, Supplier will store, secure and insure the Products and have them properly packaged and identifiably destined for Client (conditioned where necessary). Any associated reasonable costs may be charged after prior consultation with Client and Written confirmation from Client. Client will confirm the arrangements regarding these costs within eight calendar days after they are made.
- 7.9 Inspection, reviews and/or testing of the Performance by Client pursuant to provisions in article 16 do not imply approval of delivery or purchase. Nor does signing for receipt imply approval of the delivered Performance.

- 7.10 If Supplier intends to discontinue production and/or marketing of Products ordered on a regular basis by Client in due course, it will notify Client<sup>1</sup> thereof as soon as possible, but at least 3 months prior to the possibility of placing a final Order. Products already ordered by Client will be delivered at any time.
- 7.11 If the Performance to be delivered by Supplier is subject to export regulations or export licences, Supplier will promptly indicate In Writing and in a structured manner to Client which of these are applicable.

#### Artikel 8 Packaging and Shipment

- 8.1 The Product must be packaged and labeled properly in accordance with applicable European and national laws and regulations, as well as any additional requirements from Client, in such a way that the Product reaches Client in good condition.
- 8.2 Supplier is responsible for damage caused by inadequate packaging. Supplier will arrange for pick-up or the return of damaged Products and will deliver a new (undamaged) version of the Product within 2 working days without Client incurring additional costs. In case of damage, if Client judges that there is a need for urgency, Supplier will deliver within a shorter period of time, without incurring additional costs for Client.
- 8.3 The content of the packing is clearly visible from the outside and has a verifiable description. If the content of the packing is to be cooled, kept sterile or otherwise requires special storage, this will be clearly legible on the packing.
- 8.4 All packing materials (excluding loaned packing materials) will be the property of Client at delivery, unless Parties agree otherwise. In the event of the latter, article 8.6 of this GPC applies in full. Supplier must specify in the packing list accompanying the Product if the Product is packed with loaned packing materials. Moreover, the loaned packing materials must be clearly characterised by Supplier as such. If it concerns loan packaging with deposit, Supplier must register it and provide this registration upon request from Client.
- 8.5 If a sterile packaged Medical Device for single use is involved, Supplier must comply with the latest VDSMH guideline "Requirements for the supply of sterile medical devices for single use".<sup>2</sup> Supplier will also arrange for the following when applying the ID code:
- the number of ID codes on the packaging is minimal.
  - the information is maximally concentrated within a single ID code and is not dispersed across different ID codes.
  - a suitable placement of the ID code on the packaging, so that the ID code can be scanned in a user-friendly manner by Client.
- 8.6 A return shipment of loaned packing materials by Client is at the expense and risk of Supplier to a destination specified by the latter. A return shipment of loaned packing materials must occur within 14 days after Client has notified Supplier of this return shipment in Writing.
- 8.7 If Supplier processes or destroys packing materials by request of Client, this will be at the expense and risk of Supplier.

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<sup>1</sup> As is also included in the July 2022 Statement of Intent 'Commitment communication for highest possible security of supply of medical devices.'

<sup>2</sup> The VDSMH is the Association for Experts of Sterile Medical Devices in Dutch Hospitals. Please see <https://www.vdsmh.nl/over-ons>

- 8.8 Supplier will comply with the most current version of the Packaging Management Decree [Besluit Beheer Verpakkingen] and its Essential Requirements [Essentiele Eisen]. At Client's request, Supplier will demonstrate that the packaging delivered complies with this.
- 8.9 If requested by Client, Supplier will, within three months, submit a plan for making packaging more sustainable and possibly taking back packaging and will enter into discussions with Client on how to reduce packaging waste.
- 8.10 In the performance of the order, Supplier will deploy vehicles that meet at least emission class 5 and have a soot filter. Applicable to both LDV (light duty vehicle, <3.500 kg) and HDV (heavy duty vehicle, >3.500 kg). At Client's request, Supplier will provide evidence of the vehicles used for the execution of the order.

#### Article 9 Ownership/Property

Ownership/Property of the Product, including parts of the Product, will transfer after full receipt of payment, unless both Parties agree otherwise. Upon delivery, Client gets the unrestricted right to use the Product. If it is agreed between the Parties that the Product must first be approved by Client through an acceptance procedure, ownership will not pass until after approval by Client.

Supplier guarantees that the full and unencumbered ownership of the Product is transferred. The Product is also free from attachments.

#### Article 10 Auxiliary materials

- 10.1 Materials made available by Supplier or purchased or manufactured by Supplier at Client's expense, unused or unprocessed raw and auxiliary materials and other Auxiliary Materials and Documentation remain Client's property or become Client's property after payment. Ownership of existing intellectual property rights to Resource Materials is in principle not transferred unless explicitly agreed otherwise.
- 10.2 Supplier is obliged to send the Auxiliary Materials referred to in article 10.1 to Client no later than with the last (partial) delivery to the extent that the nature of the materials does not prevent this.
- 10.3 Changes in or deviations to the materials and Auxiliary Materials meant in article 10.1, and the adoption of these materials and Auxiliary Materials for, or tied to, any other purpose than the delivery of the Product to Client will only be permitted after prior Written consent by Client. This consent will leave the warranty obligations of Supplier unaffected.
- 10.4 Supplier warrants that all Auxiliary Materials and Documentation necessary or prescribed for achieving the purpose specified by Client will be included, even if they are not named in the Order. Upon delivery of Medical Devices that require cleaning, disinfection and sterilisation, Supplier will provide the cleaning and sterilisation instructions. Any associated validation reports will be made available on request or made digitally available for inspection by Client.

#### Article 11 Invoicing and payment

- 11.1 Supplier submits an invoice showing the cost per delivery.



- 11.2 In addition to the statutory requirements, the invoice should include at least the following information: reference and/or order number, item description, item number quantity, price and VAT rate.
- 11.3 Invoices that do not comply with Article 11.2 will initially not be paid. Client will timely inform Supplier that the invoice will not be paid for the time being and state the reason.
- 11.4 Payment of the invoice will occur within 30 days after receipt of the invoice, provided that Client approves the delivery. Should a delivery also require the approval of another body or authority, Client is authorized to suspend payment fully or in part until this approval has been obtained.
- 11.5 Client is entitled to suspend payment (partially and reasonably) if Client discovers a failure by Supplier to perform the Agreement. Client must inform Supplier of such intention and the reason(s) in Writing at the earliest convenience.
- 11.6 Part payment and/or advance payment is not applicable unless otherwise agreed in Writing. In the event of any advance payment, and instead of or next to a transfer of ownership, Client may request that Supplier issues an unconditional and irrevocable bank guarantee or liability statement to guarantee fulfilment of his obligations. The costs for this are payable by Supplier.
- 11.7 In the event of partial deliveries by Supplier or partial payments by Client, instead of or next to a transfer of ownership, Client may request that Supplier issues an unconditional and irrevocable bank guarantee or liability statement to guarantee fulfilment of his obligations. The costs for this are payable by Supplier.
- 11.8 Payment by Client will in no way constitute a waiver of any right.
- 11.9 Client is authorized to set off any amounts it owes to Supplier against claims of whatever nature it has against Supplier. Client will notify Supplier of this in Writing in advance, providing Supplier with an overview of the amounts to be offset.

#### Article 12 Quality and warranty

- 12.1 Supplier warrants that the completed Performance at the time of delivery:
- complies with what has been agreed;
  - has the properties that have been agreed;
  - are appropriate and have no Defects;
  - is in accordance with the agreed specifications and Documentation provided, with any subcontractors also meeting the set requirements;
  - is suitable for the (special) goal for which it is intended;
  - complies with statutory requirements and other governmental regulations, including European and national law and that of lower bodies;
  - complies with the safety and quality standards and/or certification used within the industry;
  - is unencumbered and free of encumbrances.
- 12.2 In the event of a Safety Notification or a Recall, once it has been determined internally at Supplier that a Safety Notification or a Recall has been defined, Supplier must immediately, but no later than within 24 hours, inform Client In Writing. Supplier will ensure an adequate and careful internal procedure for a Safety Notification or a Recall, which will be shared with Client in the manner designated by Client.

- 12.3 If an incident occurs when using Supplier's Product, Client will immediately report it to Supplier. Both Parties then initiate their own procedures to determine whether this incident is notifiable to the Healthcare and Youth Inspectorate and/or other regulators and, as a result, undertake their own action.
- 12.4 The specified direct costs arising from a Safety Notification or Recall may be charged to Supplier by Client. If the Safety Notification or Recall results in the Product no longer being able to be used as agreed, Supplier will also take all measures to offer an equivalent alternative, the price of which cannot exceed the price of the original Product (as set out in the price list).
- 12.5 Supplier will be obliged to stipulate to its suppliers that they will also transfer directly to Client any guarantee certificates and resulting guarantees transferred to Supplier by any third parties for Parts to be delivered or supplied by them. Failure to provide such a guarantee certificate (or have it provided) does not release either Supplier or the third parties engaged by it from any relevant obligations. If discrepancies occur between different guarantee texts concerning the same Component, the guarantee text most favourable to Client prevails.

#### Article 13 Documentation

- 13.1 Supplier warrants that all Documentation necessary or prescribed for achieving the purpose specified by Client will be made available. This Documentation has been prepared in the Dutch language or, if not possible, in the English language.
- 13.2 Client is free to reproduce all Documentation for its own use.
- 13.3 If a Product and/or packaging has safety data sheets, Supplier must always provide these sheets immediately and unsolicited.
- 13.4 Supplier ensures that new versions of the Documentation referred to in Articles 13.1 and 13.3 are sent to Client free of charge and without delay.
- 13.5 At Client's request, Supplier provides a manual describing how to apply the Product in an energy-, water- and chemical-saving manner (if applicable).
- 13.6 At Client's request, Supplier will provide instructions on how to disassemble and reassemble the Product in order to replace only a broken Part or to offer the Parts separately for reuse/recycling.

#### Article 14 (Spare) Parts

- 14.1 Supplier is obliged to keep Parts of Products to be supplied available, including Spare and Consumable Parts and Items and Auxiliary Materials, for the Usual Life from the actual date of delivery or installation (assuming conditions of normal use) and to supply them on call unless otherwise agreed between the Parties.
- 14.2 The prices of the (Spare) Parts referred to in Article 14.1 are determined on the basis of the agreed price for the first delivery of the Product. A price list of the (Spare) parts concerned will be added to the Agreement. These prices can only be increased if indexation is agreed In Writing (as set out in article 5.1).

- 14.3. Supplier commits to notify Client in Writing without delay in the event of impending stagnation of the possibility of subsequent delivery of original (Spare) Parts of the delivered Product. Supplier will also take all measures to offer equivalent alternatives whose price cannot exceed the price of the original (Spare) Parts (as laid down in the price list referred to in article 14.2).

#### Article 15 Commissioning Products

- 15.1 Client will, in consultation with Supplier, ensure that all preparations have been made and all necessary infrastructural and installation measures required for the placement, commissioning, operation, use and application of Products have been taken.
- 15.2 If consumables and reusables are required for the proper use of the Products, Supplier will deliver the materials required for proper use at the same time as the delivery of the Products, unless otherwise agreed.
- 15.3 Prior to commissioning new Products, Supplier will ensure that proper user instructions have been given to Client's relevant personnel. This user instruction should also focus, where relevant, on support services e.g. technical service and the sterilisation department.

#### Article 16 Inspection, Control and/or Testing

- 16.1 Examination, inspection and/or testing by Client or persons or bodies designated by Client for that purpose may take place both prior to, during and after delivery of the Performance.
- 16.2 To this end, Supplier provide access to locations where the Product is being produced or stored and cooperate with all desired inspections, controls and testing and at his expense issue required Documentation and information if the inspection occurs prior to delivery.
- 16.3 Supplier promptly notifies Client of the time of the inspection, control and/or testing.
- 16.4 Supplier is authorized to be present during the inspection, control and/or testing.
- 16.5 If inspection, examination and/or testing after delivery results in the Performance being rejected in whole or in part, Client will report this In Writing to Supplier. Supplier must then immediately replace the Product. The risk of the Product, rejected after delivery, passes to Supplier after the Written declaration has been sent by Client.
- 16.6 If the Performance, regardless of the results of any inspection, check and/or test, does not meet the provisions of article 12 (quality and warranty) of these GPC and the Product as such does not function adequately according to Client, Supplier will at its own expense repair or replace the Products at Client's discretion upon first request.
- 16.7 In urgent cases and if, after consultation with Supplier, it must reasonably be assumed that Supplier cannot or will not (in time) properly provide for repair or replacement, Client has the right to carry out repair or replacement himself or have it carried out by third parties at Supplier's expense.

- 16.8 If Supplier fails to take back the rejected Deliverable within a reasonable time after the date of the Written notification, Client is entitled to return the Deliverable at Supplier's expense and is entitled to credit any Deliverable already invoiced within 14 calendar days, all without prejudice to Client's other rights.
- 16.9 Interim inspections, examinations, trials and/or tests or the absence thereof will not affect Client's rights in respect of the Performance.

#### Article 17 Intellectual Property and other (similar) rights

- 17.1 Parties will refrain from using the other party's name directly or consequentially for publications and/or advertisements or otherwise without prior permission from the other party.
- 17.2 Supplier guarantees that the use of the Product, including the resale of the Product, or the use of the Auxiliary Materials purchased or manufactured by it on behalf of Client, will not infringe any patent rights, trademark rights, model rights, copyrights, database rights, rights to know-how or other (intellectual property) rights of third parties.
- 17.3 If the Performance and/or anything connected with the Performance is subject to intellectual property rights and/or other (similar) rights with Supplier or third parties, Supplier is obliged to automatically and immediately grant Client a non-exclusive, non-cancellable (sub)use licence for an indefinite period of time with respect to those rights, if that (sub)use licence is required by Client for the purposes of the Performance. If there is a Product where resale is not excluded, such resale includes the non-exclusive non-cancellable (sub)use licence for an indefinite period of time.
- 17.4 Notwithstanding the provisions of Article 17.3, all intellectual property rights arising in the development of a Performance, specifically commissioned by Client, are vested in Client, unless otherwise agreed in Writing by the Parties. The rights, insofar as they (will) be vested in Supplier, are transferred to Client by Supplier's signing of an Agreement or by Client's Written acceptance of the Quotation, to be accepted by Client immediately after these rights have arisen. Insofar as the transfer of such rights would require a further deed or other formalities to be completed, Supplier will, at Client's first request, lend its cooperation to the transfer of such rights, without being able to impose conditions. Supplier hereby waives any personality rights to which it may be entitled, to the extent permitted by applicable regulations. Supplier guarantees that the employees or subcontractors involved on its side in the employment contract or contract of assignment applicable between these employees or subcontractors and Supplier waive any personality rights to which they are entitled towards Supplier, to the extent the applicable regulations permit such a waiver.
- 17.5 Supplier will indemnify Client against third-party claims arising from any (alleged) infringement of the rights referred to in this article. Supplier will immediately inform Client In Writing about the claims of those third parties under provision of all relevant documents and keep Client informed of the follow-up. Client will leave (the manner of) settling the claim to Supplier and will never make any commitments. Supplier will see to it that the infringing Product is modified so that it can be used undisturbed or provide another, functionally equivalent, Product. If this is not reasonably possible, Supplier will, upon return of the infringing Product, compensate Client for the residual book value.

## Article 18 Confidentiality

- 18.1 Parties will keep all information and/or data, which can reasonably be suspected to be confidential in nature and which has come to their knowledge in any way through the Agreement strictly confidential towards third parties, with the exception of third parties engaged for the execution of the Agreement. The parties will not disclose any information about the delivered Performance to third parties, unless with the prior Written consent of the other party, unless disclosure is made pursuant to a statutory obligation or court order. The confidentiality obligations mentioned in this article do not pertain to:
- a) information/data that was already publicly available at the time it was made available;
  - b) information/data that has become publicly available after it became available, unless this is due to the Parties' failure to comply with its obligations under this Article; or
  - c) information/data that the Parties have lawfully obtained or become aware of before such information/data was made available to the Parties.
- 18.2 The provisions of Article 18.1 do not apply, to the extent possible under the Competition Act and European competition law, to Purchasing Combinations or formal partnerships in which Client participates.
- 18.3 If a legal obligation or court order demands that information is shared that was obtained in the context of fulfilling the Agreement, Parties will immediately notify each other of this in Writing.
- 18.4 Supplier undertakes towards Client to impose the obligations mentioned in clause 18.3 on those (including employees) charged with the performance of the Agreement.
- 18.5 If Supplier breaches its obligations under this article, Supplier will forfeit an immediately payable penalty of EUR 25,000 (twenty-five thousand euros) excluding VAT per event to Client, such penalty not affecting Supplier's obligation to pay any compensation. Parties may depart from this in Writing.

## Article 19 Information security and protection of personal data

- 19.1 Supplier conforms to the applicable regulations regarding information security in healthcare (such as but not limited to NEN7510 Standard for Information Security in Healthcare or an equivalent international standard) and ensures that the Performance it provides is in accordance therewith. Supplier gives Client permission to audit the process and the Performance or have it audited by means of an (external) information security audit, if Client sees reason to do so as a result of (suspected) information security or privacy incidents. Internal costs for the audit are borne by the Parties, external costs for an external audit are borne by Supplier if imperfections are found. Supplier guarantees that the Performance does not contain any security measures or functions other than those specified in the Documentation or contain elements foreign to the ICT Performance (malware such as, but not limited to, viruses, hidden keys, Trojan horses or other obstructions).
- 19.2 Parties guarantee that all applicable European and legal regulations concerning the data to be processed, including in particular but not limited to regulations by or pursuant to the General Data Protection Regulation (AVG), the AVG Implementation Act (UAVG) and medical confidentiality within the Medical Treatment Agreement Act (WGB0), have been and will be complied with strictly.
- 19.3 Supplier will promptly provide Client with information on this matter requested in Writing. Supplier will ensure appropriate security of the personal data. Supplier will indemnify Client for all third-party claims and penalties that may be instituted/imposed against Client for violation of applicable laws and regulations regarding the processing of personal data.

- 19.4 If Supplier is a data processor within the meaning of the AVG, the agreements between Client and Supplier with regard to the processing of personal data (including indirectly traceable personal data) will be laid down in a data processor's agreement in accordance with the health care industry association's (BOZ) model thereof.
- 19.5 Agreements between Client and Supplier on the transfer of personal data where both Parties are data controllers will be laid down in a data exchange agreement.
- 19.6 When Client and Supplier are joint controllers for the processing of personal data, the agreements on this joint processing are laid down in a Joint Controllers' Agreement in which, to the extent possible, the provisions of the most recent BOZ model data processor agreement apply.

#### Article 20 Liability

- 20.1 Supplier will be liable for damage suffered by Client or by third parties (including but not limited to patients, visitors, persons acting on behalf of Client and subcontractors) as a result of a Defect in its Performance and/or as a result of or in connection with the performance of the Agreement, unless the Parties have agreed otherwise. Supplier is also liable for the damage suffered by Client or third parties as a result of an attributable failure of any obligation under the Agreement by Supplier, such damage arising from the Performance delivered by Supplier to Client. Supplier is not liable for reputational damage, damage caused by force majeure within the meaning of articles 21.9 to 21.11, depreciation of Products and loss of turnover and/or profit.
- 20.2 Supplier's liability for orders for which the agreed price for the Agreement or contract value is less than or equal to EUR 125,000 (one hundred and twenty-five thousand euros) excl. VAT is limited per event to an amount of EUR 625,000 (six hundred and twenty-five thousand euro) excluding VAT with a maximum of EUR 1,250,000 (one million two hundred and fifty thousand euro) excluding VAT per calendar year.
- Supplier's liability for orders for which the agreed price for the Agreement or contract value is higher than EUR 125,000 (in words: one hundred and twenty-five thousand euros) excluding VAT is limited per event to an amount of EUR 1,250,000 (in words: one million two hundred and fifty thousand euros) excluding VAT with a maximum of EUR 2,500,000 (in words: two million five hundred thousand euros) excluding VAT per calendar year.
- Supplier's liability for orders that are subject to mandatory public procurement or are covered by the Procurement Act 2012 and for which the agreed value of the Order is equal to or more than the relevant threshold amount set by the European Commission is limited to EUR 2,500,000 (two million five hundred thousand euros) excluding VAT per event with a maximum of EUR 5,000,000 (five million euros) excluding VAT per calendar year.
- 20.3 The aforementioned limitation in Article 20.2 of liability lapses:
- in case of third-party claims for damages resulting from death or injury;
  - if there is intent or gross negligence on the part of Supplier, its personnel or others such as personnel of/and subcontractors employed by Supplier;
  - in case of infringement of intellectual property rights and other (similar) rights as referred to in article 17 of this GPC;
  - in case of statutory liability which cannot be limited;
  - in case that limitation of liability is otherwise contrary to the regulations in force;
  - in case liability arises from the protection of personal data (article 19).

- 20.4 Client's liability to Supplier is limited to a maximum amount of EUR 500,000 (five hundred thousand euro) excluding VAT per calendar year.
- 20.5 Supplier indemnifies Client against third party claims under this Agreement (including but not limited to subcontractors, the tax authorities or social security authorities).
- 20.6 Supplier will ensure that it is adequately insured for its liability under this article during the term of the Agreement. At Client's request, Supplier will provide proof of insurance coverage, showing that Supplier is adequately insured. If applicable, upon Client's request, Supplier will provide proof of payment of premiums due in this respect. Supplier is required to assign to Client all claims as regards insurance sums paid that are tied to a claim submitted to Client.

#### Article 21 Suspension, dissolution and termination and force majeure

- 21.1 Without prejudice to all other statutory and contractual rights to rescind or terminate the Agreement, Client is entitled (1) to rescind or terminate the Agreement, as well as any related Agreements, in whole or in part, with immediate effect by means of a registered letter without judicial intervention, without being liable to pay any compensation, and/or (2) to suspend its payment obligation towards Supplier, if:
- a) Supplier fails to fulfil its obligation(s) under the Agreement, or fails to do so on time or properly. If performance is not permanently impossible, dissolution can only be invoked after Supplier has been given notice of default by Client by means of a Written notice of default and has been granted a reasonable period of time to perform and after the reasonable period of time to perform has expired Supplier still fails to perform these obligation(s);
  - b) Supplier has applied for suspension of payments or has been granted definitive suspension of payments or Supplier is applying for (voluntary or statutory) debt restructuring or is in bankruptcy;
  - c) Supplier (being a natural person) has submitted a request to have the Natural Persons Debt Rescheduling Act applied or this request has been granted;
  - d) all or part of Supplier's assets are seized;
  - e) Supplier (being a natural person), is placed in receivership;
  - f) Supplier proceeds to discontinue or transfer its business or an important part thereof, including, but not limited to, the transfer of its business into a company to be incorporated or already existing, or proceeds to change the objective of its business;
  - g) in case of shutdown, liquidation or full or partial takeover, merger or any similar situation resulting in a (significant) change in ownership and/or control at Supplier;
  - h) if any benefit has been or is offered or provided by Supplier or any of its subordinates or representatives to a person, who is part of Client's company or to any of its subordinates or representatives without Client's prior Written consent.

A dissolution or termination or suspension of payment obligations as referred to under a to h of this article will not affect any other rights to which Client is entitled under the foregoing including Client's right to compensation.

- 21.2 Client is entitled to terminate the Agreement based on a deficiency that arises out of article 16.7.
- 21.3 If Client requires a change as referred to in article 4 and the proposal for price and/or delivery time is unreasonable in the opinion of Client given the nature and scope of the change, Client will have the right to terminate the Agreement through a Written notification to Supplier. Dissolution based on this paragraph will not give Parties a right to compensation for damage.



- 21.4 If Client is entitled to terminate, Client is also authorized to terminate any Associated Maintenance agreements and other Associated Agreements, even if there are no independent shortcomings in these Agreements.
- 21.5 In the event of an attributable shortcoming on the part of Supplier, Supplier will be required to compensate Client for any extrajudicial and judicial costs.
- 21.6 Supplier will not be entitled to invoke any right of suspension or power of set-off towards Client unless there is a suspension of payments or bankruptcy of Client.
- 21.7 All claims held by Client over Supplier in cases referred to in this article will be due and payable immediately.
- 21.8 If due to changed European or national regulations or a court ruling that has become res judicata and the present Agreement is (entered into) in violation of applicable tendering rules, Client is entitled to dissolve the Agreement without judicial intervention. In that case, Client is not required to compensate Supplier for any damage of whatever nature or scope owed to this dissolution.
- 21.9 Force majeure means the inability to perform an Agreement due to a non-attributable failure. Force majeure on the part of Supplier does in any case not include: lack of personnel, strikes, illness of personnel, automation problems, late delivery within the area of influence of Supplier or unsuitability of materials or of the system software, breach of contract by third parties engaged by Supplier and/or liquidity or solvency problems on the part of Supplier.
- 21.10 If the Parties cannot fulfil their obligations to each other due to force majeure, those obligations will be suspended for the duration of the force majeure.
- 21.11 Supplier will only be able to invoke force majeure if it notifies Client thereof as soon as possible, accompanied by the necessary supporting documents. If the force majeure situation on the part of Supplier has lasted longer than one month and there is no agreed suitable solution, Client is entitled to dissolve the Agreement in whole or in part by means of a registered letter and without judicial intervention. Invoking Force Majeure on the part of Supplier does not affect Supplier's obligation to seek alternatives to nevertheless deliver the Performance and to minimise the damage resulting from the Force Majeure.

## Article 22 Termination

In case of an Agreement for an indefinite period, the Parties are always authorized to terminate the Agreement. For Supplier, the notice period is at least twelve months. Client takes into account a notice period of at least four months. Consequently, Client is not liable to pay compensation to Supplier. Unjustifiably received discounts by Client are excluded from this.



#### Article 23 Continuing obligations

Obligations that are by their nature intended to continue after the end of the Agreement will continue to exist after the end of the Agreement and Associated Agreements. These obligations include:

- keeping (Reserve) Parts available during the Usual lifespan (article 14);
- indemnification for violation of intellectual property and other (similar) rights (article 17);
- confidentiality obligations (article 18);
- personal data protection (article 19);
- liability (article 20);
- applicable law and address for service (article 24).

#### Article 24 Applicable law and disputes

- 24.1 The Dutch law, including applicable codes of conduct such as the Code of Conduct for Medical Devices, exclusively applies to the Agreements to be concluded by the Parties and all Agreements resulting therefrom or related thereto. The applicability of the Vienna Sales Convention is excluded.
- 24.2 Any disputes which could arise as the result of the Agreement or Agreements arising out of it will be brought before a competent judge in the district of Client.

#### Article 25 Procedure for Display or Trial shipment/placement

- 25.1 Client must provide a Written order ('trial placement order') to Supplier. The Model Agreement for Medical display or trial shipment/placement is applicable if agreed in Writing.
- 25.2 Supplier confirms in Writing when the desired or agreed Display or Trial placement starts and ends, as well as on which day the Display or Trial placement will be picked up by Supplier if Client has not taken the decision to buy the Product and agreement has been reached on the purchase before that time. Medical aids intended as a Trial shipment/placement are delivered clean and ready for use in healthcare by Supplier.
- 25.3 Supplier confirms in Writing when the desired or agreed Display or Trial shipment is sent, as well as on which day the Display or Trial shipment must be returned by Client if Client has not decided to buy the Product by that time and agreement on the purchase has been reached. A trial shipment is delivered complete, clean, and ready for operational use by Supplier.
- 25.4 All proposals from Supplier regarding purchase, intake, or other agreements regarding the Display or Trial shipment/placement on approval must be submitted in Writing to Client. Supplier can only claim rights against Client after Client has accepted the proposals in Writing.
- 25.5 Supplier provides Client with sufficient consumables free of charge, unless used for direct patient care, to properly evaluate the Display or Trial shipment/placement on approval during the trial period.
- 25.6 Supplier bears the full risk for the Display or Trial shipment/placement, unless there has been gross negligence or carelessness on the part of Client during the trial period in the use of the Display or Trial shipment/placement.

#### Article 26 Ownership and Risk in Lease

- 26.1 In case of Lease, Supplier remains the owner of the Products that he has leased to Client and Supplier continues to bear the risk and will adequately insure himself in this regard. For the Lease, Client owes no reimbursement or compensation, save for the reimbursement of used disposables. If a Leased product shows Deficiencies or wear, Supplier will at the request of Client replace or repair the Product at his own expense, unless Client has failed to take proper care of the Product. The parties make arrangements regarding maintenance.
- 26.2 Client will handle the Products during the Lease as a good caretaker.
- 26.3 Supplier may retrieve Products that have been Leased after consultation with Client, or if the agreed period has expired. In the event of a Recall or Safety Notification, the provisions in articles 12.2 and 12.4 will be adhered to.

#### Article 27 Ownership and Risk in Consignment

- 27.1 Supplier retains the risk of the Products in Consignment until the moment Client takes the Product into use. The taking into use is seen as delivery.
- 27.2 Supplier will replenish the stock of Products by the next working day at the latest, after Client has informed Supplier through an Order that he has taken or intends to take the Products from Supplier into use.
- 27.3 Supplier commits to insuring the products in Consignment until the moment risk transfers to Client pursuant to article 27.1.
- 27.4 Client will use the Products during the Consignment responsibly.
- 27.5 In the case of Consignment, Supplier invoices after receiving confirmation that the Product has been taken into use by Client.
- 27.6 Supplier may take back Products sent in Consignment after consultation with Client, or if the agreed period has lapsed. In the event of a Recall or Safety Notification, the provisions in articles 12.2 and 12.4 will be adhered to.
- 27.7 If after approval and the taking into use of Products by Client it has become apparent that the Products do not satisfy set requirements, Client is entitled to complain to Supplier within 14 days after discovering a possible Defect. In this case, Client will not be liable for a decrease in value of the Product.

#### Article 28. Safety, Environment and Corporate Social Responsibility

- 28.1 Supplier accepts that he is responsible for the effects of his activities on the environment, employees, and the society in which he operates. Supplier strives to establish a structured CSR policy, possibly a CSR action plan, and will provide a CSR report to Client upon request.

- 28.2 Supplier will comply with (supra)national and local environmental legislation and will take measures to protect the environment in the broadest sense of the word. Supplier will organize its business processes in such a way that compliance is ensured. Supplier will be proactive and, where possible, innovative, in order to continuously improve its environmental performance in relation to the delivery of Products and/or Services.
- 28.3 Supplier strives to limit the amount of waste as much as possible and to process it in a way that minimizes the impact on the environment. Supplier supports Client in the environmentally conscious disposal of waste generated by the delivery of the Services.
- 28.4 Supplier applies the universal labor standards outlined in a series of conventions by the United Nations International Labour Organization (ILO).
- 28.5 If Supplier also provides housing for the employees available, Supplier must have two contracts with the employee: one for performing the work and one for renting the housing. These two contracts must not be linked in any way. Supplier will provide access to the relevant contracts to Client upon request.
- 28.6 Supplier will treat employees equally regarding the nature of work and work intensity, and ensure all have equal opportunity.
- 28.7 Supplier will reward work on equal levels equally.
- 28.8 At the request of Client, Supplier is willing to provide the Raw Material Passport, as far as possible and if applicable, for a Product.
- 28.9 At the request of Client, Supplier is willing to make the chain of suppliers of a Product transparent to the extent possible.
- 28.10 Supplier will, at the request of Client, demonstrate the CO2 footprint throughout the life cycle of the Performance.
- 28.11 Supplier strives to offer a high level of Circularity for its Products. Upon request from Client, Client and Supplier agree on KPIs for Circularity.
- 28.12 Supplier is proactive and, where possible, innovative in improving the environmental performance of the Products or Services to be delivered.
- 28.13 Client has the goal of acting in line with the national sustainability objectives (e.g. Climate Accord, Netherlands Circular 2050, Chain Approach Medicine Residues from Water, National Prevention Accord). At the request of Client, Supplier will make an effort to make a plan with Client on how the delivered Product or Service can contribute to the national sustainability objectives.
- 28.14 At the request of Client, Supplier will indicate which Highly Concerned Substances (HCS) are present in its Product, packaging, and in what concentrations (grams per gram). Once that request has been made, Supplier will keep Client informed of changes regarding the composition or legislation regarding HCS.

## ADDITIONAL SERVICE CONDITIONS

### Article 29 Personnel, equipment and materials

- 29.1 Any personnel engaged by Supplier in the performance of the Agreement must demonstrably meet the special requirements laid down by Client, as well as the general requirements of professional competence and expertise (qualified and competent).
- 29.2 If, in the opinion of Client, Supplier does not engage sufficient qualified personnel, Supplier is obliged, on Client's demand, to replace such personnel without delay, subject to the provisions of article 29.1. In all other cases, Supplier only completely or temporarily replaces personnel engaged long-term at Client if there is a genuine need and only after prior consultation with Client. New personnel will at least have the same knowledge and experience as the replaced personnel, without this resulting in higher costs for Client. The replacement will not result in costs for Client pertaining to the transfer of work.
- 29.3 Client has the authority to inspect and test all materials and equipment to be used by Supplier in performance of the Agreement and to identify personnel to be used by Supplier in performance of the Agreement.

### Article 30 Client's terrain, buildings and infrastructure

- 30.1 Before performance of the Agreement commences, Supplier must become familiar with circumstances on the terrain and in the buildings of Client where the work is to be performed that may influence performance of the Agreement.
- 30.2 Supplier ensures that its presence and the presence of its personnel on Client's premises and in Client's buildings do not impede the uninterrupted progress of Client's and third parties' work and related processes.
- 30.3 Client's business operations may not be interrupted as a result of Supplier's work unless previously discussed and agreed to in Writing by Client.
- 30.4 During the work, Client's processes remain in operation. Nuisance-causing work should be avoided as much as possible and/or planned in consultation with relevant Client departments.
- 30.5 Tests and work that may interfere with Client's business operations must first be submitted to Client. Execution of this work may only take place after Client's express Written consent.
- 30.6 Before commencing performance of the Agreement, Supplier and its personnel must familiarise themselves with the contents of the house and conduct rules, regulations and codes of conduct applicable on Client's premises and in Client's buildings, including those relating to safety, health and the environment, and conduct themselves accordingly. In this connection, Supplier or its personnel and/or subcontractors will in any case report to the officers to be designated by Client.