

GCE GROUP GENERAL BUSINESS TERMS AND CONDITIONS



GCE

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PREAMBLE

1. These General Conditions shall apply when the parties agree in writing or otherwise thereto. Deviations from the Conditions shall not apply unless agreed in writing.

When used in these conditions the term "written" or "in writing" refers to a document signed by both parties or a letter, fax, electronic mail or other means agreed by the parties.

PRODUCT INFORMATION

2. Data in product information and price lists are binding only to the extent that they are expressly referred to in the contract.

TECHNICAL DOCUMENTS AND TECHNICAL INFORMATION

3. All drawings and other technical documents regarding the goods or their manufacture submitted by one party to the other, prior or subsequent to the formation of the contract, shall remain the property of the submitting party.

Drawings, technical documents or other technical information received by one party shall not, without the consent of the other party, be used for any other purpose than that for which they were submitted. They may not without the consent of the other party be copied, reproduced, transmitted or otherwise communicated to a third party.

4. GCE shall, not later than by delivery of the goods, free of charge provide the Customer with one copy, or the larger number of copies that may have been agreed, of drawings and other technical documents, which are sufficiently detailed to permit Customer to carry out installation, commissioning, operation and maintenance (including running repairs) of all parts of the goods. GCE shall not, however, be obliged to supply manufacturing drawings of the goods or spare parts.

DELIVERY TEST

5. Where a delivery test has been agreed, it shall, unless otherwise agreed, be carried out where the goods are manufactured.

If technical requirements for the test have not been agreed, the test shall be carried out in accordance with general practice in the industry concerned in the country where the goods are manufactured.

6. GCE shall notify Customer in writing of the delivery test in sufficient time to permit Customer to be present at the test.

If Customer has received such notice, the test may be carried out even if Customer is not represented at the test. GCE shall record the test. The test report shall be sent to Customer. The report shall, unless otherwise shown by Customer, be considered to correctly describe the execution of the test and its results.

7. If at the delivery test the goods are found not to be in accordance with the contract, GCE shall as soon as possible ensure that the goods comply with the contract. If so required by Customer a new test shall thereafter be carried out. Customer may not, however, require a new test if the defect was insignificant.
8. If no other division of the costs has been agreed, GCE shall bear all costs for delivery tests carried out where the goods are manufactured. Customer shall, however, at such delivery tests bear all costs for his representatives, including costs for travel and subsistence.

DELIVERY

9. Where a trade term has been agreed, it shall be interpreted in accordance with the INCOTERMS in force at the formation of the contract. If no trade term is specifically agreed, the delivery shall be Ex Works.

TIME FOR DELIVERY. DELAY

10. If, instead of a fixed date for delivery, the parties have agreed on a period of time within which delivery shall take place, such period shall start to run at the formation of the contract.
11. If GCE finds that he will not be able to deliver the goods at the agreed time or if delay on his part seems likely, he shall without undue delay notify Customer thereof in writing, stating the reason for the delay and if possible the time when delivery can be expected. If GCE fails to give such notice, he shall, regardless of the provisions of Clauses 13 and 14, reimburse Customer for any additional expenses, which the latter incurs and which he would have avoided, had he received notice in time.
12. If delay in delivery is caused by a circumstance which under Clause 36 constitutes ground for relief or by an act or omission on the part of Customer, including suspension by GCE under Clause 18, the time for delivery shall be extended by a period, which is reasonable having regard to the circumstances in the case. The time for delivery shall be extended even if the reason for delay occurs after the originally agreed time for delivery.

13. If GCE fails to deliver the goods on time, Customer is entitled to liquidated damages from the date on which delivery should have taken place. The liquidated damages shall be payable at a rate of 0.5 per cent of the agreed price for each complete week of delay. If the delay concerns only a part of the goods, the liquidated damages shall be calculated on the part of the price which is properly attributable to the part of the goods which cannot be taken in use due to the delay. The liquidated damages shall not exceed 7.5 per cent of that part of the price on which it is calculated.

The liquidated damages become due at Customer's written demand but not before all of the goods have been delivered or the contract is terminated under Clause 14.

Customer loses his right to liquidated damages if he has not lodged a written claim for such damages within six months after the time when delivery should have taken place.

14. If Customer is entitled to maximum liquidated damages under Clause 13, and the goods are still not delivered, Customer may in writing demand delivery within a final reasonable period which shall not be less than one week.

If GCE fails to deliver within such final period and this is not due to any circumstance for which Customer is responsible, Customer may, by written notice to GCE, terminate the contract in respect of that part of the goods which cannot be taken in use due to the delay. In case of such termination Customer shall also be entitled to compensation for the loss he suffers because of GCE's delay to the extent that the loss exceeds the maximum of liquidated damages which Customer may claim under Clause 13.

This compensation shall not exceed 7.5 per cent of that part of the price which is properly attributable to the part of the goods in respect of which the contract is terminated.

Customer shall also have the right to terminate the contract by written notice to GCE if it is clear that there will be a delay, which under Clause 13 would entitle Customer to maximum liquidated damages. In case of termination on this ground Customer shall be entitled to both maximum liquidated damages and compensation under the third paragraph of this Clause. Except for liquidated damages under Clause 13 and termination of the contract with limited compensation under this Clause 14, all other claims in respect of GCE's delay shall be excluded.

This limitation of GCE's liability shall not apply, however, where GCE has been guilty of gross negligence.

15. If Customer finds that he will be unable to accept delivery of the goods on the agreed date, or if delay

on his part seems likely, he shall without undue delay notify GCE thereof in writing stating the reason for the delay and, if possible, the time when he will be able to accept delivery.

If Customer fails to accept delivery on the agreed date, he shall nevertheless make any payment which is dependent on delivery as if the goods in question had been delivered. GCE shall arrange storage of the goods at Customer's risk and expense. If Customer so requires, GCE shall insure the goods at Customer's expense.

16. Unless Customer's failure to accept delivery as referred to in Clause 15 is due to any such circumstance as described in Clause 36, GCE may by written notice require Customer to accept delivery within a reasonable period.

If, for any reason for which GCE is not responsible, Customer fails to accept delivery within such period, GCE may, by written notice to Customer, terminate the contract in respect of that part of the goods which is ready for delivery but has not been delivered due to Customer's default. GCE shall then be entitled to compensation for the loss he has suffered by reason of Customer's default. The compensation shall not exceed that part of the price which is properly attributable to the part of the goods in respect of which the contract is terminated.

PAYMENT

17. Unless otherwise agreed, the agreed purchase price, together with value added tax, if any, shall be invoiced with one third at the formation of the contract, one third when GCE gives written notice that the bulk of the goods are ready for delivery. Final payment shall be invoiced at delivery of the goods. The invoiced amount becomes due 30 days after the date of the invoice.

18. If Customer fails to pay, GCE shall be entitled to interest from the due date at the rate of interest determined by the law on late payments in GCE's country.

If Customer fails to pay by the due date, GCE shall also, after having notified Customer in writing thereof, suspend performance of his contractual obligations until payment is made.

19. If Customer has failed to pay the amount due within three months after the due date, GCE may terminate the contract by written notice to Customer and, in addition to interest on late payment, claim compensation for the loss he has suffered. The compensation shall not exceed the agreed purchase price.

RETENTION OF TITLE

20. The goods shall remain the property of GCE until paid for in full, to the extent that such retention of title is valid.

LIABILITY FOR DEFECTS

21. GCE shall, in accordance with the provisions of Clauses 23–33 below, remedy any defect in the goods resulting from faulty design, materials or workmanship. GCE provides instruction for installation where applicable and offer product training to installers but due to several local legal requirements in different markets stipulating further competence and certification of installers as well as testing, approval, recording and certification of installation, the installer shall take responsibility of competence of installers, or workmanship and records of installations. GCE is not liable for defects arising out of material provided by Customer or a design stipulated or specified by him.
22. GCE's liability does not cover defects caused by circumstances, which arise after the risk has passed to Customer. The liability does not, for example, cover defects due to conditions of operation deviating from those anticipated in the contract or to improper use of the goods. Nor does it cover defects due to faulty maintenance or incorrect installation from Customer's side, alterations undertaken without GCE's written consent or faulty repairs by Customer. Finally the liability does not cover normal wear and tear or deterioration.
23. GCE's liability is limited to defects which appear within a period of one year from the date of delivery of the goods. If the goods are used more intensely than agreed, this period shall be reduced proportionately.
24. For parts, which have been repaired or replaced under Clause 21, GCE shall have the same liability for defects as for the original goods for a period of one year. For other parts of the goods the liability period referred to in Clause 23 shall be extended only by the period during which the goods could not be used due to a defect for which GCE is liable.
25. Customer shall notify GCE in writing of a defect without undue delay after the defect has appeared and in no case later than two weeks after the expiry of the liability period defined in Clause 23 as supplemented by Clause 24. The notice shall contain a description of how the defect manifests itself. If Customer fails to notify GCE in writing within the above time limits, he loses his right to make any claim in respect of the defect. If there is reason to believe that the defect may cause damage, notice shall be given forthwith. If notice is not given forthwith, Customer loses the right to make any claim based on damage which occurs and which could have been avoided if such notice had been given.
26. In the event that a serious concern of product safety is identified regarding a GCE product GCE will issue a Field Safety Notice or initiate a recall. In such cases GCE customers, including distributors, are obliged to forward the information to the concerned customers and end users as well as support the collection of products in case of a recall. In case of serious incidents or accidents involving GCE products GCE must be informed and, if possible, the product made available for analysis. Description of circumstances leading up to an accident and other equipment connected helps GCE with such an analysis.
27. After receipt of a written notice under Clause 25, GCE shall remedy the defect without undue delay. Within this limit the time for remedial work shall be chosen in order not to interfere unnecessarily with Customer's activities. GCE shall bear the costs as specified in Clauses 21–32. Remedial work shall be carried out at Customer's premises unless GCE finds it appropriate to have the defective part or the goods sent to him for repair or replacement at his own premises. GCE shall carry out dismantling and re-installation of the part if this requires special knowledge. If such special knowledge is not required, GCE has fulfilled his obligations in respect of the defect when he delivers a duly repaired or replaced part to Customer.
28. If Customer gives such notice as referred to in Clause 25, and no defect is found for which GCE is liable, the GCE shall be entitled to compensation for the work and costs which he has incurred as a result of the notice.
29. If remedy of the defect requires intervention in other equipment than the goods, Customer shall be responsible for any work or costs caused thereby.
30. All transports in connection with repair or replacement shall be at GCE's risk and expense. Customer shall follow GCE's instructions regarding how the transport shall be carried out.
31. Customer shall bear the increase in costs for remedying a defect which GCE incurs when the goods are located elsewhere than at the destination stated in the contract or – if no destination has been stated – the place of delivery.

32. Defective parts, which have been replaced under Clause 21, shall be placed at GCE's disposal and shall become his property.
33. If GCE fails to fulfil his obligations under Clause 26 within a reasonable time, Customer may by written notice require him to do so within a final time. If GCE fails to fulfil his obligations within that time limit, Customer may at his option:
- a)have the necessary remedial work carried out and/or have new parts manufactured at GCE's risk and expense, provided that Customer proceeds in a reasonable manner, or,
 - b)demand a reduction of the agreed purchase price not exceeding 15 per cent thereof. If the defect is substantial, Customer may instead terminate the contract by written notice to GCE. Customer shall also be entitled to such termination where the defect remains substantial after measures referred to in a). In case of termination, Customer shall be entitled to compensation for the loss he has suffered. The compensation shall not, however, exceed 15 per cent of the agreed purchase price.
34. Regardless of the provisions of Clauses 21–32, GCE shall have no liability for defects in any part of the goods for more than two years from the start of the liability period referred to in Clause 23.
35. GCE shall have no liability for defects save as stipulated in Clauses 21–33. This applies to any loss the defect may cause, such as loss of production, loss of profit and other consequential economic loss. This limitation of GCE's liability shall not apply, however, if he has been guilty of gross negligence.

LIABILITY FOR DAMAGE TO PROPERTY CAUSED BY THE GOODS

36. Customer shall indemnify and hold GCE harmless to the extent that GCE incurs liability towards any third party in respect of loss or damage for which GCE is not liable towards Customer according to the second and third paragraphs of this Clause.

GCE shall have no liability for damage caused by the goods:

- a)to any (movable or immovable) property, or consequential loss due to such damage, occurring while the goods are in Customer's possession, or
- b)to products manufactured by Customer or to products of which Customer's products form a part.

The above limitations of GCE's liability shall not apply if he has been guilty of gross negligence. If a third party lodges a claim for compensation against GCE or Customer for loss or damage referred to in this Clause, the other party to the contract shall forthwith be notified thereof in writing. GCE and Customer shall be mutually obliged to let themselves be summoned to the court or arbitral tribunal which examines claims against either of them based on damage or loss alleged to have been caused by the goods. The liability as between GCE and Customer shall, however, always be settled by arbitration in accordance with Clause 39.

GROUNDS FOR RELIEF (FORCE MAJEURE)

37. The following circumstances shall constitute grounds for relief if they impede the performance of the contract or makes performance unreasonably onerous: industrial disputes and any other circumstance beyond the control of the parties, such as fire, war, mobilization or military call up of a comparable scope, requisition, seizure, trade and currency restrictions, insurrection and civil commotion, shortage of transport, general shortage of materials, restrictions in the supply of power and defects or delays in deliveries by subcontractors caused by any such circumstance as referred to in this Clause. The above described circumstances shall constitute grounds for relief only if their effect on the performance of the contract could not be foreseen at the time of formation of the contract.
38. The party wishing to claim relief under Clause 36 shall without delay notify the other party in writing on the intervention and on the cessation of such circumstance. If grounds for relief prevent Customer from fulfilling his obligations, he shall reimburse the expenses incurred by the seller in securing and protecting the goods.

39. Notwithstanding other provisions of these General Conditions, either party shall be entitled to terminate the contract by notice in writing to the other party, if performance of the contract is delayed more than six months by reason of any grounds for relief as described in Clause 36.

DISPUTES. APPLICABLE LAW

40. Disputes arising out of or in connection with the contract shall not be brought before the court, but shall be finally settled by arbitration in accordance with the law on arbitration applicable in GCE's country.

41. All disputes arising out of the contract shall be judged according to the law of GCE's country.

MEDICAL DEVICES / REQUIREMENTS IN THE TRADE IN MEDICAL DEVICES ACCORDING TO THE MEDICAL DEVICES REGULATION MDR

42. General obligations of the distributor

Definitions as per MDR:

'Distributor' means any natural or legal entity in the supply chain, other than the manufacturer or the importer, that makes a device available on the market, up until the point of putting into service;

'Economic operator' means a manufacturer, an authorised representative, an importer, or a distributor

The customer / distributor recognize his obligations and must at all times act in accordance **with MDR**

Chapter II, Article 14, "General obligations of the distributor".

a) Ensure that the information supplied with the product accompanies the product in the original document format or is included in the information package supplied.

b) In case of issues, especially vigilance cases:

a. Distributors and all economic operators shall co-operate with the manufacturer and authorities to ensure that a root cause investigation can be done. The manufacturer can then decide necessary corrective actions to either bring the device into conformity, to withdraw or to recall it as appropriate.

b. Affected products are to be made available to the manufacturer on request together with related products such as gas cylinders, valves and other equipment

c) For identification within the supply chain, economic operators such as importers, distributors and healthcare professionals are required to reach an appropriate level of traceability of products with manufacturers in accordance to **MDR Chapter III**

Article 25

d) Over a period of 10 years or at least the product lifespan as stated, economic operators must be able to inform the competent authority or the manufacturer about:

a. Any economic operator to whom they have directly supplied a device;
b. Any economic operator who has directly supplied them with a device;
c. Any health institution or healthcare professional to which they have directly supplied a device

e) In addition to obligations defined for economic operators in MDR chapter II and taking into consideration how the product is supplied and

used, especially considering patient confidentiality, the following is expected:

- a. Support market corrective actions in case of vigilance, as recall, refurbishment or distribution of safety notices by for example identification of affected users, quarantine and return of suspect products etc. as requested by GCE
- b. On request support collection of clinical and other data as input to Post market clinical follow up and post market surveillance

REGIONAL OFFICES

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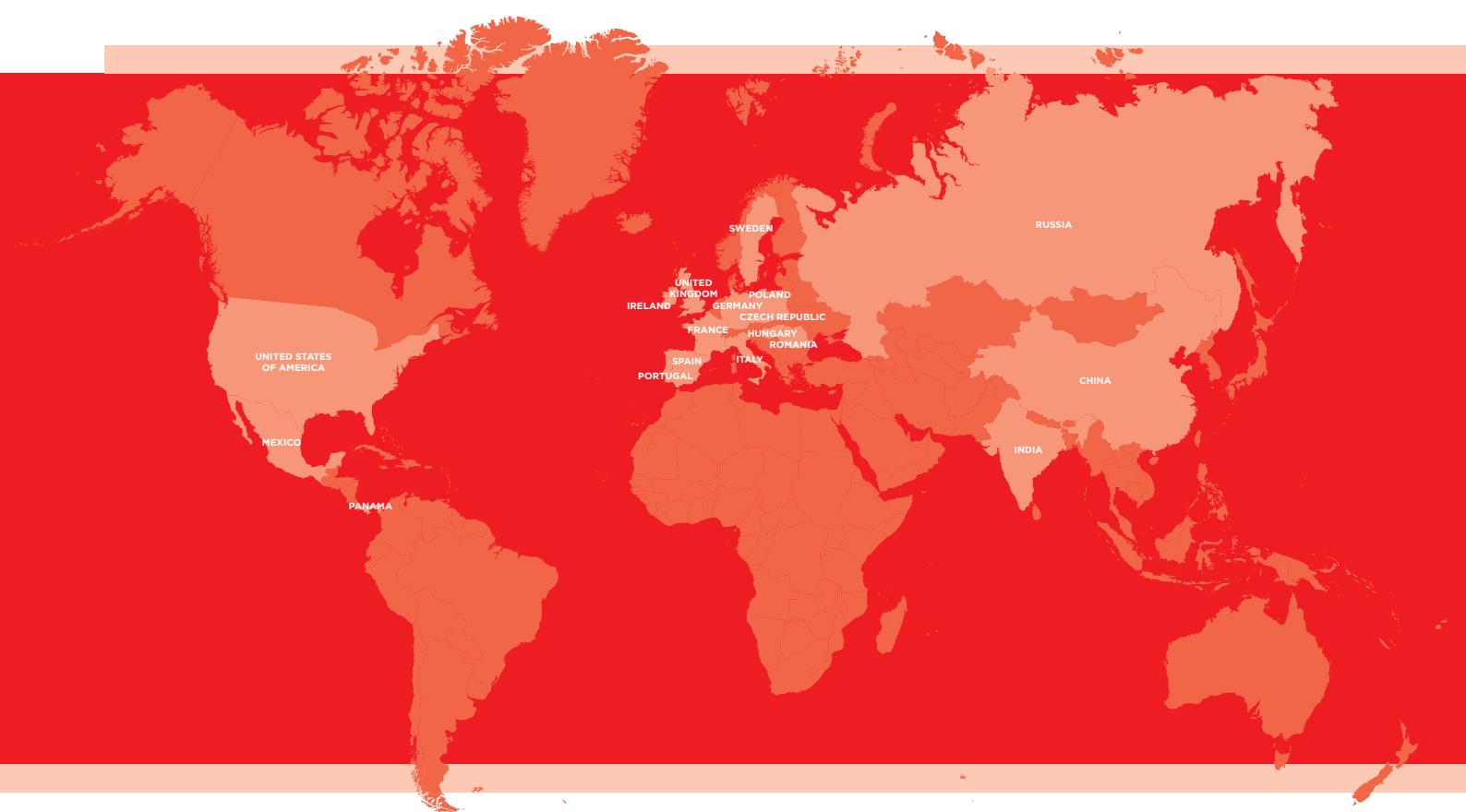
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