

§ 1

Scope of application / applicable law

1. Our Terms and Conditions of Sale for the purchase of medical devices, other goods and services apply only to companies within the meaning of § 310 para. 1 of the German Civil Code/"BGB" (hereafter referred to as "Purchasers" or "Customers"): These Purchasers are subject solely to these conditions; we do not recognise conditions that deviate from our Terms and Conditions of Sale or any different standard terms and conditions, particularly the Purchaser's standard purchasing conditions unless we have consented to the application of such conditions in writing in the particular case. Our Standard Terms and Conditions of Sale also apply should we deliver the goods to the Purchaser or provide the service ordered unconditionally, although aware of contrary conditions or conditions that differ from our own.
2. Our Terms and Conditions of Sale apply to the purchase of medical devices or other goods supplied by our parent company, Elektromedizinische Geräte Ges. m.b.H, Fürstenweg 77a, 6020 Innsbruck, Austria and to additional products and ancillary services, such as repairs and maintenance, service and services offered on behalf of third parties that we (hereafter referred to as "MED-EL Deutschland GmbH") offer for sale.
3. It is agreed between MED-EL Deutschland and the Purchaser that all matters and claims relating to goods and services will be subject to German law. The application of UN purchasing law is excluded.  
 All future transactions with the Customer concerned will also be governed by MED-EL Deutschland's Terms and Conditions of Sale.  
 All agreements made between MED-EL Deutschland and the Purchaser for the purchase of individual medical devices, other goods and services are included in text form in the relevant purchase contract.

§ 2

Nature and scope of services

1. MED-EL Deutschland regards orders it receives as an offer to conclude a contract for the purchase of medical devices or other goods or services (§ 145 BGB). We reserve the right to accept such offers within two weeks.  
 The nature and the scope of the services provided by the parties are determined by the contents of the individual orders and their acceptance. This applies to the purchase of a product by a written or verbal order and to Customers ordering other services (replacement procurements, repairs, technical support of medical personnel, intra or post-operative - for example in the case of initial or follow-up installations – as well as introductory and training courses, in each case on request). Provided MED-EL Deutschland delivers purchases or orders within two weeks of receiving the purchase application/order without reservations (see also § 2 no. 1 sentence 2), these services will be subject to MED-EL Deutschland's published price list.
2. Should the Purchaser place purchases or orders verbally or by telephone, MED-EL Deutschland will confirm this order or declaration of acceptance in text form or will fulfil the order within the period of time referred to in paragraph 1.

1. a) MED-EL Deutschland informs clinics and contracted doctors with which it already has business relationships of its current prices lists.  
 b) Officially licensed acousticians and service installations appointed by the clinic receive price lists concerning the services relevant to them, including those to be provided by MED-EL Care & Competence Center GmbH.
2. The purchase price is the fee for all contractual services. It is derived from the applicable agreements. Prices are fixed prices.
3. The prices are final prices; the deduction of cash discounts requires the written consent of MED-EL Deutschland.
4. MED-EL Deutschland will inform the Customer of the price of repairs and ancillary services on application.
5. All prices for products and ancillary services shown in quotations and invoices are net prices. The prices do not include the value added tax stipulated by law, but this will be shown separately in the invoice at the rate stipulated by law on the date the invoice is issued.  
 Should an ancillary service for MED-EL Deutschland be based on a fixed price for a period of more than six months, we will be entitled to charge the new value added tax rate six months after any change in the value added tax rate for the services to be provided at that time (price condition).
6. Unless the relevant contract states anything to the contrary, this contract is due for payment within 30 days of the invoice date. Payment arrears are subject to the relevant provisions of the law.
7. The Client will check that MED-EL Deutschland's invoice is correct immediately after having received the invoice. Should the invoice deviate from written agreements, the Purchaser is required to send a written complaint by registered letter to MED-EL Deutschland (MED-EL Elektromedizinische Geräte Deutschland GmbH, Moosstraße 7, 82319 Starnberg, enclosing a copy of the agreement, within 14 days of receiving the invoice. This deadline will have been fulfilled if the registered letter is dispatched on the last day of the deadline; otherwise the invoice price at issue will have been approved, unless the invoice difference appears to be an unacceptable discrepancy between MED-EL Deutschland's service and the price invoiced.
8. Unless agreed in writing, advance payments will not be required.

§4

Delivery time

1. The beginning of the delivery period stated by MED-EL Deutschland is conditional on all technical matters having been clarified.
2. The fulfilment of our obligation to provide the service is also conditional on the Purchaser having fulfilled its contractual obligations on time and according to contract. We reserve the right to invoke the plea of failure to fulfil a contract.
3. Any delay in acceptance by the Purchaser or its culpable failure to fulfil its obligation to cooperate will entitle MED-EL Deutschland to claim damages incurred, including any additional costs. This will not exclude the assertion of additional claims or rights.

4. Should the conditions referred to in section 3 be fulfilled, the risk of accidental destruction or accidental deterioration of the goods purchased will pass to the Purchaser at the time the delay in acceptance or in honouring obligations occurs.
5. MED-EL Deutschland is liable
  - a) for the punctual fulfilment of firm contractually agreed transactions,
  - b) also in accordance with the provisions of the law, should a delay for which MED-EL Deutschland is responsible entail the Purchaser no longer having an interest in the continued fulfilment of the contract,
  - c) in accordance with the provisions of the law, for delivery delays caused deliberately or through gross negligence on the part of MED-EL Deutschland, including our vicarious agents. Should the delivery delay be due to gross negligence, compensation will be limited to foreseeable damage, typically incurred.
  - d) in accordance with the provisions of the law, should a delay in delivery for which we are responsible be due to a culpable infringement of a major contractual obligation to the extent of and in accordance with foreseeable damage, typically incurred.

#### § 5

Operational readiness and beneficial rights to the software in the case of active implantable medical devices

1. At the Purchaser's request and at a time agreed with MED-EL Deutschland, MED-EL Deutschland will support the medical practitioner in actually putting the Cochlea Implant System concerned and the associated processor into operation after its implantation and after the operation wound has healed. As regards the technical part, this will be carried out in cooperation with the responsible clinic on a basis of trust. Medical responsibility in this situation will remain with the Purchaser's doctors.
2. The special MED-EL operating software for the Hearing Implant System is subject to domestic and international copyright laws and contracts governing intellectual property. It is part of the Hearing Implant System and can be operated through the use of the associated activation key. It may only be used as follows and as described in the manual:
  - a) Title or rights equivalent to title to the MED-EL operating software for the implants and the related audio processors remain with MED-EL Elektromedizinische Geräte Ges. m.b.H. as its developer and manufacturer.
  - b) The Purchaser or User is only entitled to use the software and the rights to the software provided for the specified purpose intended and in accordance with the contract and may also install a copy of the software product on a storage medium or for applications.  
The Purchaser or user is required to desist from any attempt to change the software. This also includes the obligation to desist from attempts to regress the product.
  - c) The Purchaser is not permitted to re-sell or to rent out the system or to carry out any other kind of transfer for use, whether for a fee or free of charge. Any use of this sort requires MED-EL Deutschland's written consent. A loan to third parties for medical reasons also requires MED-EL Deutschland's consent.
  - d) Should the software be used or processed contrary to the contract, MED-EL Deutschland is entitled to demand that the Purchaser, User and/or the third party desist, to revoke the right to use the system to the exclusion of any claims by the Purchaser, User other third parties and to demand compensation.

3. Should a condition be referred to as applicable solely to a particular Hearing Implant System, this condition will apply to all other hearing systems.

#### § 6

Transfer of title and risk, rights to use the software in the case of active medical devices

1. Title to non-implanted medical devices or parts thereof will pass to the Purchaser concerned on payment of the purchase price, unless anything to the contrary has been agreed and providing title to parts of the system can be transferred independently. The special software to operate the hearing system does not form part of the purchase contract.
2. The Purchaser of a MED-EL hearing system or parts thereof is entitled to use these products for the treatment of patients. MED-EL reserves title to the goods purchased until all payments due under the delivery contract have been made. MED-EL will be entitled to extended reservation of title to active medical devices. In the event of payment arrears, we are entitled to take back the goods purchased. Our taking back the goods purchased represents a rescission of the contract entitling us to dispose of the goods purchased. The proceeds of disposal will be deducted from the Purchaser's liability, less any reasonable costs of disposal.
3. The Purchaser of hearing systems and exchangeable parts of the same and the User each undertake to MED-EL Deutschland only to use the software provided and the rights thereto in accordance with the intended purpose and the contract and only to pass them on to third parties subject to the consent of MED-EL Deutschland; any change, any copying or any other transfer to and use of the software on other equipment require the prior written consent of MED-EL Deutschland.  
Any use or processing of the software contrary to the contract will entitle MED-EL Deutschland to demand that the User and/or the third party desist and to revoke the right to use the system to the exclusion of any claims by the Purchaser or User.

#### § 7

Liability for defects - warranty

Unless anything different is stated in the order confirmation, all services provided by MED-EL Deutschland, including for software and hardware, will be subject to the following:

1. The applicable product description in the current MED-EL prospectuses will be considered the agreed quality with regard to the absence of defects of goods delivered by MED-EL Deutschland. A minor deviation from the product description will not be considered material. Deviations from the product description that are due to circumstances for which MED-EL Deutschland, MED-EL Elektromedizinische Geräte Ges. m.b.H or their suppliers are not responsible do not form part of the warranty. This applies specifically to defects caused by third parties (also hearing aid acousticians), by Users or, after risk has passed, as a result of technical or other influences (particularly medical-surgical influences during or after the operation – e.g. mechanical damage to the electrodes, settings or changes to the software) or the impact of mechanical influences as a result of knocks, jolts or changes in pressure – e.g. sport, leisure etc – or the effects of electro-magnetic waves and magnetic fields – e.g. use of a magnetic resonance tomograph.

2. a) All services provided by MED-EL Deutschland will be subject to the legal warranty periods in purchasing law (§ 438 BGB) or the law applicable to the providers of services, unless amended in what follows.
  - b) The expiry period for the purposes of warranty will begin when the goods are delivered and, in the case of software, with the delivery of the data medium or the provision of the individual software to be downloaded.
  - c) In the case of Brain Stem and Cochlea Implants: provided the patient or his legal representative has completed and signed the “patient declaration” and returned this to MED-EL Deutschland within eight weeks of the operation, the following extended rules in favour of the patient will apply from the time MED-EL Deutschland receives the patient declaration: the expiry period for warranty claims for the implant itself begins on the day of its implantation and will last for ten years.
  - d) For active middle ear implants: the expiry period for warranty claims for the implant itself (VORP) begins on the day of its implantation and will last for five years for implants implanted before, and ten years for implants implanted after April 1, 2021.
  - e) For bone conduction implants: the expiry period for warranty claims for the implant itself (BCI) begins on the day of its implantation and will last for five years for implants implanted before, and ten years for implants implanted after April 1, 2021.
  - f) For passive middle ear implants: the expiry period for warranty claims for the implant itself (PORP, TORP and stapes prosthesis) begins on the day of its implantation and will last for two years.
  - g) For the hearing system ADHEAR: the expiry period for warranty claims for the hearing system and its software begins on the day of delivery to the place of performance and will last for two years.
  - h) For active medical devices (programming interfaces etc.) provided by MED-EL to support adaptation etc. to the hearing system: the medical devices will be handed over for use by the operator / user as part of the initial equipment but will remain the property of MED-EL Elektromedizinische Geräte Ges. m.b.H and must be returned to MED-EL on request or when use is completed. Use free of charge is governed by the provisions of the law.
3. The provisions of the law also apply to our ancillary and other services.
4. Any defects in the goods covered by warranty occurring during the warranty period must be reported to MED-EL immediately, defects in an implant must also be reported in writing.
5. MED-EL Deutschland will decide on the measures required in order to remedy a defect. The Purchaser’s right to choose in accordance with § 437 BGB will be subordinate to MED-EL Deutschland’s right to decide and may only be exercised should MED-EL Deutschland’s attempt to remedy the defect either fail on three occasions or should the elimination of the defect have been conclusively rejected.
 

Should an implant as such be affected, and should elimination of the defect be excluded, MED-EL Deutschland will replace only the implant itself after the warranty period has expired by providing a MED-EL replacement implant. Any claims in addition to these services, including the costs of the operation and consequential costs are excluded, unless the case is covered by § 444 BGB or some other mandatory provision of the law.

6. In every case in which a re-implantation is required as part of the obligation to examine a defective implant stipulated by law in accordance with Regulations of the Safety of Medical Devices (MDR) and irrespective of when the implant becomes defective, the patient agrees to an investigation of the cause of the defect and the necessary appraisal of the removed explant by MED-EL Deutschland or MED-EL Elektromedizinische Geräte Ges. m.b.H in Innsbruck and the practitioner (clinic) carrying out the re-implantation and its responsible manager undertake to have the explant returned immediately after the operation to MED-EL Deutschland and/or MED-EL Elektromedizinische Geräte Ges. m.b.H, Innsbruck, Fürstenweg 77a, A-6020 Innsbruck and to transfer title back to these companies.
7. The Purchaser of the hearing system is required to pass on all its own obligations entered into in the purchase contract to the patient.

#### § 8

##### Place of performance and transfer of risk

The place of fulfilment for services provided by MED-EL Deutschland is Starnberg provided no other place of fulfilment is stipulated in the confirmed individual order. Should a MED-EL Deutschland product be delivered from one of its delivery warehouses or by an external agent as service provider, the location of the delivery warehouse or the external agent will be considered the place of fulfilment. In cases where the products are sent, transfer of risk is considered to take place when the products are handed over to party appointed to carry out the delivery (freight forwarder, post etc.).

#### § 9

##### Concluding provisions

1. There were no verbal side-agreements at the time the contract was concluded.
2. Side-agreements made verbally or by telephone after the conclusion of a contract may only come into force with the text that was transmitted to MED-EL Deutschland in text form and that was not immediately rejected by MED-EL.
3. The text form requirement also applies to amendments to the provision of § 9 of these Standard terms and Conditions.
4. Should the Purchaser be an entrepreneur, the place of jurisdiction is MED-EL Deutschland’s registered office; we are also entitled to sue the Purchaser at the court responsible for its registered office.
5. Should a provision of the relevant individual contract or these Terms and Conditions be or become null and void or invalid, this will not affect the remaining conditions of the contracts or of these Standard Terms and Conditions. § 306 para. 2 BGB will apply.