

General Terms and Conditions of WILAmEd GmbH, Aurachhöhe 5-7, Kammerstein, Germany

1. Scope of Application

- 1.1. Deliveries and services of WILAmEd GmbH ("WILAmEd") are exclusively provided in accordance with the following provisions, unless expressly agreed otherwise at least in text form.
- 1.2. WILAmEd rejects general terms and conditions of the customer; they shall only become part of the contract if WILAmEd has expressly agreed to them in writing. The General Terms and Conditions of WILAmEd shall also apply if WILAmEd performs the service to the customer without reservation in the knowledge of terms and conditions of the customer that are contrary to or deviate from the terms and conditions of WILAmEd.

2. Offer, Conclusion of Contract, Prices

- 2.1. The offers of WILAmEd are subject to confirmation. Written and verbal orders and other agreements as well as verbal collateral agreements only become effective and binding (conclusion of the contract) upon written confirmation by WILAmEd. In case of an omitted order confirmation, the order confirmation may be replaced by the shipment of the goods.
- 2.2. For information on the intended purpose and use, the respective instructions for use for the medical device, which are part of the delivery, shall be authoritative for the delivery of medical devices.
- 2.3. Deliveries and services of WILAmEd are generally provided on the basis of the prices valid at the time of placing the order. Only in the event that the agreed period between the placing of the order and the delivery exceeds four (4) months, WILAmEd shall be entitled to charge the customer the prices applicable at the time of the delivery or service. If the customer does not agree with the then applicable prices, it may object in writing within fourteen (14) calendar days after notification of the current prices. The originally agreed prices shall then apply. After expiry of this period, the contract shall be executed at the current prices.
- 2.4. The prices are "Free Carrier" (FCA Incoterms 2020), if not expressly agreed otherwise, ex works WILAmEd's manufacturing site in Kammerstein, Germany, otherwise ex works the agreed manufacturing site of WILAmEd or distributor and in addition to the applicable statutory value added tax and other applicable taxes. WILAmEd is also entitled to pass on costs to the customer that arise due to the implementation of new, legally mandatory safety regulations in connection with the goods.
- 2.5. Insofar as special agreements are granted to the customer, these shall only apply under the condition that the customer duly fulfills its contractual obligations. A non-fulfillment entitles WILAmEd to immediately revoke the special agreements.
- 2.6. Framework supply agreements do not establish any obligation for a specific call-off and a cancellation does not establish any obligation to take over residual materials.

3. Reservation of Self-Delivery

If the delivery is not available because WILAmEd has not been supplied by its own suppliers or the stock of WILAmEd for the delivery has been exhausted, WILAmEd is entitled to provide a delivery equivalent in quality and price. If the provision of a delivery equivalent in quality and price is permanently not possible for WILAmEd, WILAmEd may withdraw from the contract.

4. Delivery, Passing of the Risk

- 4.1. Unless expressly agreed otherwise, the delivery of the goods is effected according to section 2.4 FCA ex WILAmEd plant Kammerstein, Germany, otherwise ex the agreed WILAmEd plant or distributor. WILAmEd is entitled to partial deliveries. In case of custom-made products, excess or short deliveries of up to five percent (5%) of the agreed quantity are permissible.
- 4.2. In case WILAmEd takes over the organization of the transport, the route and means of transport are subject to the choice of WILAmEd, subject to a special agreement.
- 4.3. The risk shall pass to the customer in a case pursuant to clause 4.3 upon handover of the goods to the carrier or other transporter.
- 4.4. Goods that have been reported ready for shipment must be picked up immediately. If this does not happen, WILAmEd is entitled to ship them at the expense and risk of the customer at WILAmEd's discretion or to store them at WILAmEd's discretion and to invoice them immediately, including costs for storage according to clause 5.5.
- 4.5. WILAmEd does not conclude a separate transport insurance. Should the customer wish to have a transport insurance, he has to take it out himself and at his own expense.
- 4.6. In case of a delivery of disposable items due to a faulty order, WILAmEd may refuse the return.

5. Time of Delivery

- 5.1. If not included in an order confirmation, the determination of delivery and execution deadlines shall require a special written agreement.
- 5.2. In the above case, deadlines shall not commence before final determination of all commercial and technical prerequisites for the execution of the order.
- 5.3. The compliance with the delivery obligation of WILAmEd further requires the timely and proper fulfillment of the obligation of the customer. The defense of non-performance of the contract remains reserved.
- 5.4. If WILAmEd is in default, the customer may set a reasonable grace period of at least two (2) weeks with the declaration.
- 5.5. If shipment or delivery is delayed at the request of the customer by more than one (1) month after notification of readiness for shipment, WILAmEd may charge the customer storage fees in the amount of zero point five percent (0.5%) of the net price of the delivery, however, not exceeding a total of five percent (5%) of the net price of the delivery, as a lump sum for each month or part thereof. The parties shall be at liberty to prove higher or lower storage costs.

6. Force Majeure

In cases of force majeure, in particular in case of war, natural disasters, sovereign acts, global pandemics, strikes, lockouts, riots, disruptions in the supply of energy and raw materials, extraordinary traffic and road conditions, sovereign measures and interventions as well as other operational disruptions for which WILAmEd is not responsible, WILAmEd is entitled, irrespective of whether these circumstances occur at WILAmEd or a supplier, to postpone the delivery for the duration of the hindrance or, if an end of the hindrance is not foreseeable, to withdraw from the contract in whole or in part without further obligations. § Section 313 BGB remains unaffected.

7. Customer's Rights in Case of Material Defects

- 7.1. The parts of a delivery that show a material defect within the warranty period shall, at the discretion of WILAmEd, be repaired, redelivered or provided again free of charge ("subsequent performance"), provided that the cause of the material defect already existed at the time of the transfer of risk.
- 7.2. No new warranty period shall commence as a result of subsequent performance (7.3).
- 7.3. Claims for material defects shall become statute-barred after twelve (12) months. This does not apply insofar as § 445b and 634a para. 1 no. 3 BGB (German Civil Code) prescribe longer periods as well as in cases of injury to life, body or health, in case of an intentional or grossly negligent breach of duty by WILAmEd and in case of fraudulent concealment of a defect.

The statutory provisions on suspension of expiry, suspension or recommencement of time limits shall remain unaffected.
- 7.4. The customer shall immediately check the contractual conformity of the delivery as well as the preliminary and intermediate products and data sent to him upon receipt in accordance with § 377 HGB (German Commercial Code).
- 7.5. The customer shall notify WILAmEd of any material defects immediately, at the latest two (2) weeks after receipt of the delivery ("notice of defects"). Later notices of defects are excluded, unless the customer proves that these are material defects which could not have been discovered even in case of a proper and thorough inspection. The notice of defects shall include the communication of the data concerning the delivery: Product name, number of the invoice or the order confirmation of WILAmEd, as well as description of damage or defect.
- 7.6. A right of retention of the customer does not exist if its warranty claims are time-barred. If the notice of defect was unjustified, WILAmEd is entitled to demand compensation from the customer for the expenses incurred in this context.
- 7.7. WILAmEd shall be granted the opportunity for subsequent performance within a reasonable period of time. If WILAmEd is denied the opportunity of subsequent performance as described under clause 7.1 or is thwarted by the customer, in particular because not enough time is granted, WILAmEd is released from the liability for material defects.
- 7.8. Claims for defects shall not exist in the case of only insignificant deviation from the agreed quality or in the case of only insignificant impairment of the usability within the scope of a customary tolerance and otherwise within the tolerance specified in Clause 7.10, in the case of natural wear and tear or damage occurring after the transfer of risk as a result of incorrect or negligent handling, excessive stress, unsuitable treatment agents, or due to special external influences which are not assumed under the contract. In particular, this also includes the use of equipment, which may only be used by instructed personnel, by uninstructed personnel.
- 7.9. Defects in a part of the delivery shall not entitle the Customer to complain about the entire delivery, unless the entire delivery is no longer usable for the Customer.
- 7.10. Excess or short deliveries of up to 10% of the ordered quantity cannot be objected to. The basis for invoicing shall be the quantity delivered. Short deliveries of up to 10% of the ordered print run shall therefore not be deemed to be a material defect and shall not entitle the customer to make claims based on liability for material defects or to make claims for damages.
- 7.11. Claims by the customer for expenses incurred for the purpose of subsequent performance, in particular transport, travel, labor and material costs, are excluded insofar as the corresponding expenses increase because the delivery has subsequently

been taken to a place other than the place of performance or other special requests are to be taken into account.

- 7.12. The customer's right of recourse against WILAmEd only exists insofar as the customer has not made any agreements with its purchaser that exceed the statutory claims for defects. 7.8 to 7.11 apply accordingly to the scope of the customer's right of recourse against WILAmEd.
- 7.13. Further or other claims of the customer against WILAmEd due to a material defect than those regulated in 7. are excluded. This does not apply in case of fraudulent concealment of the defect, in case of non-compliance with a quality guarantee, in case of injury to life, body, health or freedom and in case of an intentional or grossly negligent breach of duty by the supplier. A change in the burden of proof to the detriment of the customer is not associated with the above provisions.

8. Infringement of Property Rights, other Defects in Title

- 8.1. Unless otherwise agreed, WILAmEd shall provide deliveries free of industrial property rights and copyrights of third parties ("Property Rights"). If a third party asserts justified claims against the customer due to the culpable infringement of Proprietary Rights by a delivery provided by WILAmEd and used by the customer in accordance with the contract, WILAmEd shall be liable within the period stipulated in 7.3 as follows:
 - 8.1.1. WILAmEd shall, at its own choice and at its own expense, either obtain a right of use for the delivery in question, modify the delivery in such a way that the property right is not infringed or replace the delivery.

If this is not possible for WILAmEd under reasonable conditions, the customer is entitled to the statutory rights of withdrawal or reduction.

The regulations in 7.6, 7.7 and 7.12 apply accordingly.
 - 8.1.2. The fulfillment of the aforementioned obligations requires that the customer immediately notifies WILAmEd in writing of the claims asserted by the third party, that it does not acknowledge an infringement and that WILAmEd reserves the right to all defensive measures and settlement negotiations. If the customer discontinues the use of the delivery for reasons of mitigation of damages or other important reasons, it is obliged to point out to the third party that the discontinuation of use does not imply any acknowledgement of an infringement of property rights.
- 8.2. Claims of the customer are excluded insofar as the customer is responsible for the infringement of property rights.
- 8.3. Claims of the customer are furthermore excluded, if the infringement of the property right is caused by special specifications of the customer, by an application not foreseeable by WILAmEd or by the fact that the delivery is modified by the customer or used together with products not delivered by WILAmEd.
- 8.4. In the event of other defects of title, the provisions of 7 shall apply accordingly.
- 8.5. Further or other claims of the customer than those regulated in 8. due to a defect of title against WILAmEd and its vicarious agents are excluded.

9. Compliance with legal requirements, authorized representatives, advertising materials

- 9.1 The legally compliant action of the customer is assumed by WILAmEd and is the business basis of the contract. The compliance with applicable laws also applies to processes that

are subject to safety regulations, such as approval, installation, operation and maintenance of medical devices. If a legal violation on the part of the customer can be proven, WILAmEd reserves the right to terminate the contract.

- 9.2 The conditions for fulfilling quality and regulatory obligations, implementation of Regulation EU 2017/745 (MDR) and distributor obligations in the supply chain are regulated in Annex 1.
- 9.3 In certain countries, WILAmEd GmbH has appointed authorized representatives who are mainly responsible for the registration of the products and/or the import of the products. A list of these authorized representatives is attached as appendix 2. The list does not claim to be complete.
- 9.4 The customer undertakes to use only advertising materials approved by WILAmEd. No responsibility will be assumed for deviating advertising.

10. Customer's Obligation to Release from Liability

- 10.1. The customer shall immediately release WILAmEd against all claims of third parties that are raised against WILAmEd in connection with the delivery.
- 10.2. This obligation to release from liability does not apply if and to the extent that WILAmEd has acted intentionally or negligently vis-à-vis the customer or the third party.
- 10.3. The above provisions shall not imply a reversal of the burden of proof to the detriment of the customer.

11. Impossibility, Adaption of the Contract

Insofar as the delivery is impossible and the customer is entitled to claim damages, the customer's claim for damages shall be limited to a maximum of 10% of the value of that part of the delivery which cannot be used by the customer due to the impossibility. This shall not apply if liability is mandatory in cases of intent, gross negligence or initial incapacity or due to injury to life, body or health. This does not imply a change in the burden of proof to the disadvantage of the customer. The right of the customer to withdraw from the contract remains unaffected.

If circumstances related to the contract, such as in particular the economic importance and/or the content of the delivery change significantly or if external circumstances, such as in particular events of force majeure according to clause 6, have a significant impact on the operation of WILAmEd, the contract will be adjusted appropriately in good faith. Insofar as this is not economically justifiable for WILAmEd, WILAmEd is entitled to an immediate right of termination or withdrawal. § Section 313 is not restricted by this. If WILAmEd intends to make use of its right of termination or withdrawal, WILAmEd has to inform the customer immediately after having realized the consequences of the event, even if an extension of the delivery time was initially agreed upon with the customer.

12. Liability, Right of Cancellation and Withdrawal

- 12.1. WILAmEd is liable according to the statutory provisions, both if the customer asserts claims for damages that are based on intent or gross negligence, including intent or gross negligence of representatives or vicarious agents of WILAmEd, and in case of culpable breach of an essential contractual obligation. As far as WILAmEd is not accused of intentional breach of contract, i.e. in case of gross negligence, and in case of breach of an essential contractual obligation, the liability of WILAmEd is limited to the foreseeable, typically occurring damage.
- 12.2. Should WILAmEd be in default of delivery due to the culpable violation of a non-substantial contractual obligation, and

provided that the customer is entitled to claim damages as a result thereof, the customer is nevertheless entitled to claim a lump-sum compensation for default in the amount of no more than five percent (5%) of the delivery value for the part of the delivery that could not be used by the customer due to the default.

- 12.3. Apart from that, liability for damages is excluded. In this respect, WILAmEd is in particular not liable for damages that have not occurred to the delivery item itself. Claims resulting from injuries to life, body or health as well as mandatory statutory liability remain unaffected.
- 12.4. The customer shall only have the right to terminate or withdraw from the contract if it has set WILAmEd a reasonable period of time in writing to make up the delivery after the expiry of the agreed period of time, combined with the declaration that it will refuse to accept the delivery after the expiry of the period of time and if this period of time has then expired without success.
- 12.5. The processing of goods delivered by WILAmEd is at the risk of the customer. The processing proposals of WILAmEd are non-binding, also with regard to possible property rights of third parties, and do not release the customer from its own examination of their suitability and purposes.
- 12.6. WILAmEd does not assume any liability for product defects outside the sphere of influence and responsibility of WILAmEd. This concerns in particular a use, maintenance and/or repair deviating from the manufacturer's information, as well as the use of not appropriately trained personnel for work on the products of WILAmEd. Likewise, WILAmEd does not assume any liability in case the products are stored and/or kept improperly deviating from the manufacturer's information or in any other way, as well as in case the products are damaged during their distribution.
- 12.7. Any claims for damages shall become statute-barred within twelve (12) months from the statutory commencement of the limitation period, unless WILAmEd is charged with intent or gross negligence or mandatory statutory provisions, in particular claims for damages under the Product Liability Act, lead to a different period.
- 12.8. A change in the burden of proof to the detriment of the customer is not associated with the above provisions.

13. Payments, Set-Off, Chargeback Consequences, Invoice Form

- 13.1. Invoice amounts are to be paid immediately and without deductions in the currency Euro. Any payment costs incurred shall be borne by the customer.
- 13.2. Payments shall always be credited against the oldest outstanding claims, even if the customer has made a different provision.
- 13.3. Offsetting with disputed and not legally established counterclaims and retention on the basis of such claims shall be inadmissible.
- 13.4. If it is agreed that WILAmEd will debit the fee from the customer's account, in case of a failed debit, the customer shall bear the costs for this and WILAmEd is entitled to send the following deliveries cash on delivery. In addition, a lump sum in the amount of EUR 25,- is due for the processing effort on the part of WILAmEd.
- 13.5. Invoices may be transmitted either on paper or electronically. The invoice recipient declares his consent to electronic invoice transmission.

14. Interests on Arrears, Default of Payment

- 14.1. If the due date pursuant to 13.1 is exceeded, interest on arrears shall be charged in accordance with Section 288 (2) BGB. The assertion of further damage caused by default shall remain unaffected.
- 14.2. Before the full payment of due amounts including interest and possible costs, WILAmEd is not obliged to further deliveries of expiring contracts.
- 14.3. If the customer is in default with a due payment or if WILAmEd should become aware of circumstances that make the creditworthiness of the customer appear doubtful, WILAmEd may immediately call due all outstanding claims, even if they have been deferred, security has been given for them or bills of exchange have been issued.

In this case, WILAmEd is entitled, without prejudice to further rights, to execute outstanding deliveries only against advance payment, to demand securities or to withdraw from contracts after a reasonable grace period or to claim damages.

In particular, WILAmEd is entitled to terminate the agreement without notice if an application for the opening of insolvency proceedings against the assets of the customer has been filed.

- 14.4. If the Customer is in default, the Customer may also be charged for any additional expenses incurred as a result (e.g. obtaining information) in addition to the usual default damages.

15. Reservation of Proprietary Rights, Testing Devices

- 15.1. WILAmEd reserves the title to the delivered goods until all claims to which it is entitled from the business relationship with the customer, including interest as well as possible costs, have been paid. In case of a current account, the reserved property shall be considered as security for our balance claim.
- 15.2. The goods subject to retention of title are exclusively intended for the consumption of the customer. A resale requires the prior written consent of WILAmEd.
- All claims arising from a resale, including any securities, are hereby assigned by the customer to WILAmEd in the amount of the purchase price claims as security. In the event that the goods subject to retention of title are sold together with other goods not belonging to WILAmEd, the claim from the resale is assigned to WILAmEd in the amount of the invoice value of the goods subject to retention of title.
- 15.3. Insofar as the retention of title is asserted due to a not insignificant delay in payment, the assertion does not also constitute a withdrawal from the contract at the same time, unless WILAmEd expressly declares this in writing.
- 15.4. The pledging or transfer by way of security of goods subject to retention of title to third parties is excluded. The customer is obliged to ward off all accesses to and impairments of the property of WILAmEd as well as to objects that are not the property of WILAmEd but have been provided to the customer by WILAmEd, irrespective of the legal ground, and to notify WILAmEd immediately. Insofar as the third party is not in a position to reimburse WILAmEd for the judicial and extrajudicial costs of a possible lawsuit, the customer shall be liable for the loss thus incurred by WILAmEd.
- 15.5. In case of default of payment, cessation of payments or application for insolvency by the customer or one of its creditors, WILAmEd is entitled, without prejudice to any further rights, to take back the Reserved Goods and to sell them otherwise. The proceeds, less all costs and expenses in connection with the sale, which WILAmEd may, at its discretion, charge at a flat rate of ten percent (10%) of the proceeds of the sale without any special proof, will be credited to the customer's total debt. Any surplus shall be paid out. The

customer is, however, entitled to prove to WILAmEd that the costs and expenses for the sale of the goods subject to retention of title are actually lower than provided for above.

- 15.6. If the realizable value of all securities to which WILAmEd is entitled exceeds the coverage limit not only temporarily by more than ten percent (10%) and if the market value or the production costs exceed the nominal amount of the secured claim by more than one hundred and fifty (150%), WILAmEd is obliged to release securities to this extent at the request of the customer, at the discretion of WILAmEd.
- 15.7. If test devices are provided to the customer, the customer may use them for 30 days free of charge. Subsequently, the customer shall immediately either return the provided test devices to WILAmEd of its own accord and at its own expense or pay the applicable purchase prices.

16. Representations and Warranties, Guarantees

- 16.1. The employees of WILAmEd are not entitled to deviate from the content of contracts by verbal or written promises or assurances or to supplement the content of the contract. This does not apply to promises or assurances by managing directors and authorized signatories as well as persons of WILAmEd authorized by them for this purpose.
- 16.2. Guarantees may only be issued by managing directors or authorized signatories of WILAmEd. Insofar as employees, who have not been granted procuration, issue guarantee promises, these are invalid.
- 16.3. Unless otherwise agreed upon in writing, any warranty given by WILAmEd for a delivery is a "bring-in warranty", i.e. in any case of a warranty service, any transport or freight costs incurred for the delivery and the pick-up shall be paid by the customer.

17. Insurance

- 17.1. Objects that are only temporarily provided to the customer for use or under reservation of title shall be insured by the customer against damage and destruction at the respective replacement value.
- 17.2. Upon WILAmEd's request, the customer has to prove the existence of the insurance coverage.

18. No Assignment

The customer is not entitled to transfer or assign any rights or claims to third parties.

19. Succession

The customer is obligated to notify WILAmEd of any change, in particular of its company name or legal form, without being requested to do so. The customer is liable for any disadvantages resulting from an omitted or delayed notification.

20. Data Protection

Customer data is stored within the scope of Art.6 I DSGVO exclusively for business purposes. Data will only be passed on to third parties in accordance with the statutory provisions or with the consent of the contractual partner. For the rest, reference is made to the data protection declaration of WILAmEd. This can be viewed on the homepage and upon request.

21. Disposal of Electrical Appliances

- 21.1 Old devices, i.e. devices that are no longer serviceable, can be returned free of charge after prior agreement with Customer Service.
- 21.2 The End User itself shall be responsible for ensuring that any personal data located on the Old Device is completely deleted before it is returned.
- 21.3 End users must separate used batteries and/or used accumulators, as well as lamps that are not enclosed by the used device, from the device before returning it, provided that this can be done non-destructively and without problems using commercially available tools. The manufacturer's instructions must be observed in this regard.
- 21.4 The symbol of the crossed-out wheeled garbage can indicates the collection of electrical and electronic equipment separately from unsorted municipal waste.
- 21.5 Distributors of electrical equipment have an obligation to take back old equipment free of charge in accordance with Section 17 (1) and (1) of the Electrical and Electronic Equipment Act (ElektroG).

22. General Provisions

- 22.1. Place of performance for deliveries by WILAmEd is, unless expressly agreed otherwise, the WILAmEd plant Kammerstein, Germany. Otherwise, the agreed WILAmEd plant or the distribution partner named by WILAmEd. For all other services, the place of performance is Kammerstein, Germany.
- 22.2. The legal relations of WILAmEd with the customer are exclusively subject to the law of the Federal Republic of Germany with the exclusion of the uniform international sales law or corresponding conflict of laws provisions, as well as the United Nations Convention on Contracts for the International Sale of Goods of April 11, 1980. Excluded from this choice of law are mandatory consumer protection provisions of the country in which the customer has its habitual residence, provided that the customer is a consumer.
- 22.3. If the customer is a merchant, if the customer does not have a general place of jurisdiction in Germany, if the customer moves its domicile or habitual residence out of the territory of the Federal Republic of Germany after the conclusion of the contract or if its domicile or habitual residence is unknown at the time of filing an action, the exclusive place of jurisdiction for all disputes shall be the court responsible for the registered office of WILAmEd (responsible local court: AG Schwabach, responsible regional court: LG Nürnberg-Fürth), Germany. To the extent permitted by law, WILAmEd may also sue the customer at the court of its general place of jurisdiction.

Fulfillment of quality and regulatory obligations, implementation of Regulation EU 2017/745 (Medical Device Regulation - MDR), distributor obligations in the supply chain.

Role as economic operators within the meaning of the MDR

WILAméd and the customer act as economic operators in the sense of the MDR. If the customer makes a product of WILAméd available on the Union market until the time of putting into service without importing it from a third country, the customer assumes the role of a distributor according to Art. 4 No. 34 MDR. WILAméd assumes the role of a manufacturer according to Art. 4 No. 30 MDR, provided that WILAméd is the legal or actual manufacturer of the product and does not only act as a distributor itself. In this case, the following regulations apply in particular:

1. Compliance with the relevant regulations

WILAméd and the Customer shall comply with the rules and regulations of the MDR applicable to the relationship of the economic operators and shall support each other in the fulfillment of the obligations resulting therefrom for them respectively. The customer undertakes to comply with the obligations according to Art. 14 MDR in its function as distributor according to Art. 4 No. 34 MDR. This includes above all

- 1.1 formal testing obligations, as well as information obligations in the event of non-conformity before products are made available on the market (Art. 14 Abs. 2 MDR);
- 1.2 Storage and transport of products according to manufacturer's specifications (Art. 14 Abs. 3 MDR);

2. Quality assurance and testing obligations

The economic operators shall maintain a quality assurance system sufficient for their roles as defined in the MDR. In particular, the economic operators shall comply with the following requirements and regulations, whereby the specifically applicable version or the corresponding superseding regulation shall be decisive in each case:

- 2.1 Medical Device Regulation or Directive (MDR or MDD, for legacy devices, as per MDCG 2020-6) - to be complied with by both economic operators;
- 2.2 EN ISO 13485: 2016 requirements for quality management systems for medical devices for regulatory purposes - to be complied with by the manufacturer, to be verified by the distributor;
- 2.3 Quality standards described in the CE certificates for the respective devices - to be complied with by the manufacturer, to be verified by the distributor;
- 2.4 Restriction of the use of certain hazardous substances in accordance with the relevant regulations - to be complied with by the manufacturer, to be verified by the distributor;

3. Obligations of the customer (information and documentation obligations, traceability)

- 3.1 The customer agrees to document, store, keep up to date and immediately forward to WILAméd all experiences and other findings, in particular all product information and reports received from the market environment, as well as complaints and incidents, in particular with regard to the identity, quality, durability, reliability, safety, effectiveness or performance of a product.

The forwarding can be done in writing or by e-mail to: vigilanz@wilamed.de. In case of suspected serious incidents, WILAmed will be informed immediately. A retention period of 15 years from the placing on the market of the respective product applies.

- 3.2 Economic operators shall maintain a documented procedure for the receipt and retention of findings and/or notifications, as well as product traceability. They shall maintain a complaints register in accordance with the applicable regulations. The economic operators shall assist each other in these tasks, as well as in root cause analyses, and in corrective and preventive actions related to a complaint, taking into account the applicable rules and regulations, and with a risk analysis of the responsible party.
- 3.3 With regard to traceability, the customer will keep information available and documented for supervisory authorities for the duration of the aforementioned retention obligation.
- 3.4 The customer will inform WILAmed in due time in advance about any significant restriction of the operation that endangers the fulfillment of the obligations according to this clause and will take precautions for the case of incisive events, such as, in particular, the termination of the operation or an imminent insolvency, or, if requested by WILAmed, cooperate in transitional measures, so that it is possible for WILAmed to fulfill all obligations according to the MDR to a sufficient extent.

4. Obligations of WILAmed

- 4.1 In order for the customer to fulfill its obligations under the MDR, WILAmed shall provide at least the documents listed below:
 - 4.1.1 Label according to Annex I Nr. 23.2 of the MDR
 - 4.1.2 Instructions for use according to appendix I Nr. 23.4 of the MDR
 - 4.1.3 EU Declaration of Conformity (DoC) according to Annex IV of the MDR
 - 4.1.4 CE certificate (if provided for the product class)
 - 4.1.5 QMS evidence
- 4.2 The customer agrees that the provided documents may be made available to him via a so-called "Sharepoint". WILAmed and the customer will agree on the details of this separately. Further information is to be requested by the customer in writing by e-mail via info@wilamed.de.

Authorised Representatives of WILAmed GmbH

1. Switzerland (CH):

MedEnvoy Switzerland

Gothardstrasse 28

6302 Zug

Switzerland

info@medenvoyglobal.com

Vigilance: EmergoVigilance@ul.com

2. United Kingdom (UK):

OMC MEDICAL Ltd

Planet House, North Heath Lane,

Horsham, West Sussex RH12 5QE

United Kingdom

info@omcmedical.co.uk

3. Saudi Arabia (SAU):

Medical Regulations Gate

Office # 21, AL Oruba Building

Al-Oruba Street

Olayah District

Riyadh

11361

Saudia Arabia

info@mr-gate.co