

**GENERAL TERMS AND CONDITIONS FOR SALE AND SERVICES AGREEMENTS
OF ORTOALRESA (NO IVDR PRODUCTS and IVDR PRODUCTS)**

FOR NO IVDR PRODUCTS

1. SCOPE OF APPLICATION

These General Terms and Conditions for Sale and Services Agreements shall apply to the contractual relations between Álvarez Redondo S.A. (hereinafter referred to as "Ortoalresa") and its buyers, understood as the legal entity, the first Buyer in the supply chain, who is obliged to act as intermediary, (hereinafter referred to as the Buyer), arising from the sale of Products manufactured and/or commercialized under the brand Ortoalresa, (hereinafter the Product or Products) as well as the Provision of Services related to the Products such as repairs, inspections and other services, (hereinafter "the Service or Services")

The Buyer accepts without reservation the present General Terms and Conditions when placing an order for Products or Services with Ortoalresa, as well as their content, made available for review in the order confirmation, as well as being published on the web page www.ortoalresa.com.

Any updates that are implemented in the General Terms and Conditions are notified and therefore applicable to any sale made when a latest version is published on the Ortoalresa website www.ortoalresa.com.

Orders for the sale of Products and Services shall be governed in the first place by these General Terms and Conditions, which shall be completed, where right, by the particular conditions that Ortoalresa and the Buyer may agree, which shall only prevail over these, when Ortoalresa has expressly accepted them in writing.

2. OFFERS AND ORDERS

The Buyer will send Ortoalresa, in writing, the offer requests and Ortoalresa will send the reply in the same manner, within a maximum period of two (2) working days from receipt. Offers are non-binding and subject to changes.

The e-mail shall be considered enough to follow the formality that any notification between the Buyer and Ortoalresa must be in writing.

Any order placed by the Buyer shall be considered binding and shall constitute an agreement upon Ortoalresa's acceptance.

The acceptance of the order shall be made within 10 days from the reception of the order or otherwise it shall be considered to be refused, unless expressly said otherwise in the order.

Upon acceptance by Ortoalresa, the purchase order is binding and may not be changed unless Ortoalresa and the Buyer agree otherwise in writing. Under no circumstances will modifications be admitted once the Products are ready for delivery.

The delivery of the Product shall be made within the period indicated in the written order confirmation.

The delivery of the Product shall be made at Ortoalresa's warehouse under EXW Conditions, Incoterms 2020 of the International Chamber of Commerce, or at the Buyer's facilities if so, stipulated depending on the amount of the purchase order and/or the particular agreements established by the parties.

The costs derived from the transport of the Product within the Spanish Peninsular Territory shall be borne entirely by Ortoalresa provided that the amount of the sum of the Products in the invoice exceeds 1.250 €, (therefore, concepts such as VAT, the tax on fluorinated gases, packaging or any other type of commercial service that may be offered by Ortoalresa shall not be included in the calculation of this amount).

For invoice amounts of less than 1.250 € within the Spanish Peninsular Territory or more than that amount outside the Spanish Peninsular Territory, the shipping costs will be charged to the Buyer, who may choose between requesting Ortoalresa to manage the shipment through Ortoalresa's usual transportation service, in which case the shipping costs will be included in the invoice of the main order or the Buyer may use his own transport service to collect the goods at Ortoalresa's warehouse. In both cases the Buyer will be responsible for the payment of said transport costs.

Ortoalresa does not conduct, nor does it include in the standard supply of its Products, the installation and commissioning of the equipment. The installation and commissioning will be invoiced independently and may be contracted by separately or together with the main purchase contract (Buyer's order), in which case it shall appear as a line item in the Buyer's order.

Items specially manufactured for a Buyer or customized, cannot be returned.

Cancellation of orders for customized Products is only possible with the express written consent of Ortoalresa.

Deliveries of Products by Ortoalresa shall follow the mandatory legal provisions about packaging, labelling and information of the Manufacturer and the Products.

In the event of delay in delivery, Ortoalresa shall be liable for the damages that this non-fulfilment may cause, except for duly justified reasons of force majeure, with a maximum limit of one per cent (1%) for each week of non-fulfilment and a total maximum of five per cent (5%) of the total value of the Product and provided that Ortoalresa has been notified of the deadlines at the time of placing the order.

3. INTELLECTUAL AND INDUSTRIAL PROPERTY RIGHTS

Ortoalresa retains all title to, ownership, copyrights and intellectual and industrial property rights (all patents, copyrights, trade secrets, trademarks, domain names and any other intellectual or industrial property rights) in all Products and Services, including all documents, materials and other items provided to the Buyer by Ortoalresa (e.g. offers, catalogues, price lists, quotations, drawings, sketches, images, descriptions and specifications of Products and services, prototypes, etc.).

Unless the Buyer is expressly authorized in writing, the Buyer may not exploit, use, copy or change the documents, materials or other elements provided by Ortoalresa, nor make them available or distribute them to third parties without obtaining previous consent by Ortoalresa in writing.

In the event that Ortoalresa has signed a particular Non-Disclosure Agreement (NDA) with the Buyer, said Agreement shall prevail over the general Confidentiality section contained in these General Terms and Conditions.

In the event that Ortoalresa has signed a particular Software License Agreement with the Buyer, said Agreement shall prevail over the provisions of these General Terms and Conditions.

In all other cases, these General Terms and Conditions shall apply to any Software License owned by Ortoalresa, and in particular:

-The assignment to the Buyer of a non-exclusive, limited, and non-transferable license to third parties to use the Software that is authorized in relation to the Products is set up.

If the Buyer of the Product is a distributor, the Buyer shall also be granted a non-exclusive, limited license to use and distribute such Software only in addition to the main product.

-The Buyer agrees to take right steps to prevent unauthorized use and disclosure and not to destroy or remove any trademarks contained in the software license.

-All the above shall also apply to any Application or System created by Ortoalresa for the Products and Services whose use has been authorized to the Buyer.

4. INFORMATION CONTAINED IN CATALOGUES AND WEB

Ortoalresa undertakes to take the greatest possible care to ensure that the descriptions, drawings and, in general, the information contained in the catalogues and on its website are accurate, notwithstanding which, such elements will have a merely approximate value, so they are not binding, and no warranty is conferred on them, so that Ortoalresa will not assume any responsibility for any possible inaccuracies that may exist in its catalogues and website.

5. PRICES

The sales prices of the Products will be those set up in the specific offers or in the Ortoalresa rates communicated to the Buyer or in the Particular Conditions agreed between Ortoalresa and the Buyer. The corresponding taxes must be added to these prices.

Ortoalresa may change the selling prices of the Products at any time. The increase in the selling prices shall not affect orders in progress, which have been previously accepted by Ortoalresa. In the event that the Buyer places an order with an incorrect price, Ortoalresa will communicate the correction and, where applicable, its acceptance of the order provided that the Buyer modifies the order document and sends it within the following 2 days.

6. PAYMENT TERMS

The price shown in the confirmation of acceptance of the order corresponds to the net price applicable at the time of conclusion of the agreement and shall refer to EXW Incoterms 2020 Conditions of the International Chamber of Commerce and do not include statutory added value tax (VAT) and other charges for packaging, transport or insurance and other compulsory taxes or duties which shall be invoiced as extra. VAT shall be applied to the Net price on the invoice sent to the Buyer.

Payment of orders for Products or Services must be made in advance, with the delivery period confirmed by Ortoalresa in the acceptance of the order being counted from the receipt of said payment.

Only in the event that special payment terms have been agreed in writing, the payment of the order shall be paid by the Buyer within the agreed period after the issue of the corresponding invoice.

Payment of the invoiced price shall be due on the date agreed with the Buyer in accordance with Act 15/2010 of 5 July 2010 amending Act 3/2004 of 29 December 2004 which shows measures to combat overdue payment in commercial transactions.

A delay in payment by the Buyer shall give entitlement to an interest for overdue payment at the legal interest rate plus 5%. Likewise, the Buyer shall reimburse Ortoalresa for the expenses incurred in the summons and collection, including those of the Lawyer and Solicitor, even if their intervention was not mandatory.

If delivery of the Products cannot be made or is delayed due to the Buyer, payment must be made on the scheduled delivery date as if there had been no such obstacle or delay.

Ortoalresa reserves the right to charge interest and collection costs on any outstanding invoice not paid on the agreed due date in accordance with Law 15/2010 of 5 July 2010.

If the Buyer has not paid by the due date agreed with Ortoalresa, Ortoalresa may suspend its outstanding Product deliveries.

In the event of insolvency or commencement of bankruptcy proceedings of the Buyer, Ortoalresa may suspend deliveries and end the contract.

In the event of termination of the contract for any reason whatsoever, the Buyer shall be obliged to pay at once for all work performed and Products supplied, as well as to pay any damages incurred by Ortoalresa.

Ortoalresa reserves the right to charge the Buyer for handling, packaging, and transport costs if the Products are returned without default on the part of Ortoalresa.

7. PRODUCT DELIVERY

The delivery times for Product orders shall be understood to be estimated or approximate, and in no case of essential fulfilment.

Therefore, Ortoalresa will not be liable to the Buyer for any delays in the delivery of Products.

In any case, Ortoalresa will procure to deal with and supply Product orders within the deadlines agreed with the Buyer, except in cases of unforeseen circumstances or duly justified force majeure.

Ortoalresa may make partial deliveries of the order, with each partial delivery generating the corresponding payment obligation owed by the Buyer.

All deliveries made by Ortoalresa shall be made under EXW Conditions, Incoterms 2020, of the International Chamber of Commerce.

The effective delivery shall be understood to have been made at the time the Products are handed over to the Buyer or to the Buyer's Transport Company.

Exceptions to the above are the cases contained in paragraphs 7 and 8 of Point 2 in which, depending on the amount of the purchase order or the particular agreements between the parties, delivery to the agreed place of destination is required.

8. STORAGE

In the event that Ortoalresa has communicated to the Buyer the availability of the Product to be picked up and the Buyer delays in the collection of the Product for a period of more than one month (1 month), Ortoalresa shall be entitled to invoice the Purchaser for storage costs of 50,00 euros per day (counted from the communication) in which the Product, being at the disposal of the Buyer, has remained in Ortoalresa's facilities.

Upon collection, the Buyer shall be held responsible for the Product and must ensure that the storage and/or transport conditions established by Ortoalresa are met.

9. TRANSFER OF RISKS

All the Products are at the risk of the Buyer from the moment they are handed over to the Buyer or to the Buyer's Transport Company.

All the Products shall remain the property of Ortoalresa, which reserves its ownership, until all the accounts owed by the Buyer to Ortoalresa have been settled and the amounts corresponding to the invoices have been paid.

Payment shall be considered due at once and automatically at the beginning of any act or procedure in which the Buyer's insolvency is involved.

In the event that, once the payment is due and has not been paid by the Purchaser to Ortoalresa, the Purchaser has sold the Product or part of it to a third party, it shall be understood that such sale has been made acting as Ortoalresa's fiduciary agent.

The Buyer shall conduct the procedures of such sale on behalf of Ortoalresa and shall account for such actions in a separate account, at once crediting the amount obtained from the sale to Ortoalresa.

10. RESERVATION OF TITLE

Ortoalresa will continue to keep ownership of the Products delivered to the Buyer until such time as full payment of the purchase order price and other amounts owed by the Buyer because of the purchase has been made.

Until such time, the Buyer is obliged to inform Ortoalresa in writing as soon as possible of any third-party intervention in the delivered Products, possible damage or any other circumstances that may affect the Products.

If the reservation of ownership contemplated here exists, the sale, pledging or any type of transfer of the Product shall not be admissible unless expressly accepted by Ortoalresa.

In the event of resale, the price received by the Buyer must be recorded as assigned to Ortoalresa and the Buyer may inform the third-party Buyer of such assignment. Likewise, the Buyer assumes the obligation to record this in its books and invoices.

Ortoalresa reserves the right to collect the price from the third-party Buyer of the Product when the Buyer does not comply punctually with its payment obligations.

11. CLAIMS REGARDING THE PRODUCTS

Regarding the deliveries made by Ortoalresa under EXW Conditions, Incoterms 2020 of the International Chamber of Commerce, where the effective delivery shall be understood to have taken place at the moment of the Products being handed over to the Buyer or to the Buyer's Transport Company, the deadlines for making a claim shall be those contained in the following paragraphs:

The Buyer shall examine the Products, as soon as possible after receipt, to verify their conformity with the type of Product ordered, and the absence of apparent or hidden defects in them. In any case, after receiving the Products, the Buyer will have a period of 5 days to claim to Ortoalresa for a difference in type between the Products delivered and those ordered or for the existence of an apparent defect in them. If the Buyer detects a possible internal or non-apparent defect in the Products, the period available to claim to Ortoalresa will be 30 days after receipt.

With regard to the cases contained in paragraphs 7 and 8 of Point 2 in which, depending on the amount of the purchase order or the particular agreements between the parties, delivery must be made to the agreed destination and therefore Ortoalresa has sent the Products through the Transport Company contracted by the same, the recipient of the Product shall have a period of 24 hours from receipt of the Product to notify Ortoalresa of a possible defect in quantity or a visible defect in the packaging.

The Buyer's conformity shall be obtained by signing the corresponding delivery note at the same time of delivery. If the buyer does not submit his claim within the indicated period of 24 hours, Ortoalresa will not assume any responsibility whatsoever.

Ortoalresa will not accept any claims received after the expiry of the aforementioned periods. If the Buyer's claim is justified and received on time, Ortoalresa will have the sole and exclusive obligation to replace the defective Products with substitute Products and shall not be liable for any loss or damage which may arise for the Buyer as a result of delay or non-delivery of conforming Products, in particular loss of profit, loss of production or loss of benefit, in accordance with the provisions of Condition 12 below.

12. LIMITATION OF LIABILITY

The Buyer is solely responsible for the choice of the Product bought, as well as for the use or function for which it is intended. Consequently, Ortoalresa is not responsible for and does not guarantee that the Product is suitable for the technical applications intended by the Buyer, nor for achieving, in whole or in part, the aims foreseen by the Buyer when buying the Products. In this respect, the Buyer shall not be entitled to return the Products and claim the price paid.

Any technical advice provided by Ortoalresa verbally, in writing or by tests, before and/or during the use of the Product, is provided in good faith, but without guarantee.

Ortoalresa's advice does not release the Buyer from its obligation to evaluate the Product supplied to decide its suitability for the processes and uses for which it is intended.

Except for when intentional conduct or gross negligence is found, Ortoalresa shall in no event be liable for any damages suffered by the Buyer. Furthermore, any liability for indirect damages, consequential damages, non-material damages, business or environmental damages, loss of profit, loss of goodwill, or damages because of liability to third parties, is excluded.

In any case, should Ortoalresa be obliged to assume liability for damages suffered by the Buyer, such liability shall be limited to an amount equivalent to the corresponding amount appearing in the order confirmation for the Product causing the damage, unless an applicable mandatory law imposes a higher quantitative limit on Ortoalresa.

The Buyer shall be solely liable, exonerating Ortoalresa as appropriate, for any damage arising against its own employees or third parties due to improper use, storage, conservation, handling or transformation of the Products, in particular, but not limited to, when the Buyer has not observed the indications, warnings or instructions that Ortoalresa may have provided in this regard in the technical documentation provided with the Product.

Ortoalresa shall under no circumstances be liable to third parties for causes beyond its control, including non-compliance by the Buyer with the regulations applicable to the Products and chemical substances. The Buyer shall hold Ortoalresa harmless from any liability for any claims, damages and/or losses arising, directly or indirectly, from the non-fulfilment of the obligations assumed by the Buyer by virtue of their contractual relationship.

13. INSTALLATION AND COMMISSIONING

The installation of the equipment shall in all cases be the responsibility of the Buyer, who must ensure that the products had been installed correctly and safely, in accordance with the manufacturer's installation instructions, which may be previously requested from Ortoalresa, following the guidelines of good commercial practice, without risk to the health or safety of persons. Ortoalresa is not responsible for the Buyer's failure to comply with this clause.

14. WARRANTY AND RETURNS

The Products have a warranty from the manufacturer as stipulated for each Product, being 24 months from the date of invoice for the Products and 6 months from the date of invoice for spare parts or any type of service or repair, for which the date contained in the delivery note of these will be considered. Please check the General Conditions of Warranty on the web: www.ortoalresa.com.

If the Buyer detects defective Products, he must notify Ortoalresa at once and in writing, specifying at least the serial or batch number of the Product and a brief description of the defect.

After being previously authorized by Ortoalresa, any return must be made in the original packaging material and with any accessories, documentation, computer media, etc. included with the product, even if it is defective.

Once verified by Ortoalresa that there are defective Products (whether materials or services), it will proceed in accordance with the provisions of the General Conditions of Warranty on the website: www.ortoalresa.com.

After the examination of the returned Product, if it is found that it is working correctly or that the cause of the malfunction is unrelated to the Product itself, it will be returned to the Buyer with postage due, together with a charge for the duration of the intervention of the technical service for handling and verification.

The cost of sending the product to Ortoalresa's technical service will be charged to the Buyer.

Products or parts of a product that have been substituted or repaired under warranty will be guaranteed only for the remaining unexpired period of the original warranty applicable to the specific Product.

15. SERVICE CONDITIONS

All the provisions contained in these GTC shall also apply to all repairs, maintenance, inspections, or other types of services that had been specifically ordered by the Buyer to Ortoalresa.

16. OBLIGATION OF ELIMINATION

Once the use period has ended, the Buyer assumes the obligation to treat and dispose of the Product supplied by its own means and following the legal provisions in force. Furthermore, the Buyer expressly releases Ortoalresa from its obligations under art.10 paragraph 2 of the German Electrical Equipment Act (obligation to return to the manufacturer) and the rights of third parties arising therefrom. Ortoalresa's right to take over/exemption by the Buyer shall expire no earlier than two years after the final termination of the operation and the written

notification to Ortoalresa. At the express request of the Buyer, Ortoalresa may organize the return and reuse/disposal of the Product against reimbursement of the incurred costs, provided that the Product has been manufactured by Ortoalresa.

17. DATA PROTECTION AND CONFIDENTIALITY

Ortoalresa is the Controller of the Buyer's personal data and informs you that these data will be processed following the provisions of the regulations in force, Regulation (EU)2016/679 of 27 April 2016 (GDPR), and therefore the following processing information is provided to you:

Purpose of processing: Provision of the requested service, administration, and communication management of the company.

Data retention criteria: Data will be kept for as long as there is a mutual interest in maintaining the purpose of the processing and when it is no longer necessary for that purpose, it will be deleted with appropriate security measures to ensure the pseudonymization of the data or the destruction of the data.

Communication of data: Data will not be communicated to third parties, unless legally obliged to do so.

Rights of the data subject: - The right to withdraw consent at any time. - Right of access, rectification, portability, and deletion of their data and to limit or oppose its processing. - The right to submit a complaint with the supervisory authority (agpd.es) if he/she considers that the processing does not comply with the regulations in force.

Contact details to exercise your rights:

Identity: ALVAREZ REDONDO, S.A.

CIF/VAT: ESA 78757903

Postal address: C/Los Frailes 121, Pol. Ind. Los Frailes, 28814 Daganzo (Madrid).

Telephone: +34 918844016

E-mail: info@ortoalresa.com

18. INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES

Ortoalresa shall not be liable for the breach by the Buyer of intellectual property rights, for an unforeseeable use of the Products sold, for the fact that the Buyer changes the shipment or uses it together with other Products or consumables not supplied by Ortoalresa.

The documentation delivered with the Products or services will always be the property of Ortoalresa and must not be disclosed to third parties unless this is legally required or with prior authorization from Ortoalresa.

19. FORCE MAJEURE

Ortoalresa will not be liable for the non-fulfilment or delay in the fulfilment of its obligations to the Buyer, if this is caused by any fortuitous event or force majeure affecting both Ortoalresa and its suppliers or carriers, including strikes, other labor, or industrial contingencies, lack or impossibility of obtaining raw materials, etc. If the cause of force majeure is extended for more than 2 months, Ortoalresa or the Buyer may consider that the orders for Products in progress shall be cancelled without giving rise to any indemnity or compensation for the Buyer.


20. APPLICABLE LAW AND JURISDICTION

The contractual relations between Ortoalresa and the Buyer, object of the present GTC, will be governed exclusively by Spanish Law, with the exclusion of the Vienna Convention on the International Sale of Goods of 1980.

Any disputes in connection with Ortoalresa's business relations with the Buyer shall be decided with express renunciation of any other Authority that could correspond to them, to the exclusive jurisdiction of the Courts of the city of Madrid. Nevertheless, in case of non-fulfilment by the Buyer of any payment obligations derived from the present GTC, Ortoalresa may choose alternatively, to exercise the legal actions that belongs to it at the Courts of the place where the Buyer's address is found.

Date: 08/02/2024

Approval: Penélope Álvarez



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ÁLVAREZ REDONDO, S.A.

GENERAL TERMS AND CONDITIONS FOR SALE AND SERVICES AGREEMENTS OF ORTOALRESA

FOR IVDR PRODUCTS

1. SCOPE OF APPLICATION

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Unless the Buyer is expressly authorized in writing, the Buyer may not exploit, use, copy or change the documents, materials or other elements provided by Ortoalresa, nor make them available or distribute them to third parties without obtaining previous consent by Ortoalresa in writing.

In the event that Ortoalresa has signed a particular Non-Disclosure Agreement (NDA) with the Buyer, said Agreement shall prevail over the general Confidentiality section contained in these General Terms and Conditions.

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If the Buyer of the Product is a distributor, the Buyer shall also be granted a non-exclusive, limited license to use and distribute such Software only in addition to the main product.

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Payment of orders for Products or Services must be made in advance, with the delivery period confirmed by Ortoalresa in the acceptance of the order being counted from the receipt of said payment.

Only in the event that special payment terms have been agreed in writing, the payment of the order shall be paid by the Buyer within the agreed period after the issue of the corresponding invoice.

Payment of the invoiced price shall be due on the date agreed with the Buyer in accordance with Act 15/2010 of 5 July 2010 amending Act 3/2004 of 29 December 2004 which shows measures to combat overdue payment in commercial transactions.

A delay in payment by the Buyer shall give entitlement to an interest for overdue payment at the legal interest rate plus 5%. Likewise, the Buyer shall reimburse Ortoalresa for the expenses incurred in the summons and collection, including those of the Lawyer and Solicitor, even if their intervention was not mandatory.

If delivery of the Products cannot be made or is delayed due to the Buyer, payment must be made on the scheduled delivery date as if there had been no such obstacle or delay.

Ortoalresa reserves the right to charge interest and collection costs on any outstanding invoice not paid on the agreed due date in accordance with Law 15/2010 of 5 July 2010.

If the Buyer has not paid by the due date agreed with Ortoalresa, Ortoalresa may suspend its outstanding Product deliveries.

In the event of insolvency or commencement of bankruptcy proceedings of the Buyer, Ortoalresa may suspend deliveries and end the contract.

In the event of termination of the contract for any reason whatsoever, the Buyer shall be obliged to pay at once for all work performed and Products supplied, as well as to pay any damages incurred by Ortoalresa.

Ortoalresa reserves the right to charge the Buyer for handling, packaging, and transport costs if the Products are returned without default on the part of Ortoalresa.

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The delivery times for Product orders shall be understood to be estimated or approximate, and in no case of essential fulfilment.

Therefore, Ortoalresa will not be liable to the Buyer for any delays in the delivery of Products.

In any case, Ortoalresa will procure to deal with and supply Product orders within the deadlines agreed with the Buyer, except in cases of unforeseen circumstances or duly justified force majeure.

Ortoalresa may make partial deliveries of the order, with each partial delivery generating the corresponding payment obligation owed by the Buyer.

All deliveries made by Ortoalresa shall be made under EXW Conditions, Incoterms 2020, of the International Chamber of Commerce.

The effective delivery shall be understood to have been made at the time the Products are handed over to the Buyer or to the Buyer's Transport Company.

Exceptions to the above are the cases contained in paragraphs 7 and 8 of Point 2 in which, depending on the amount of the purchase order or the particular agreements between the parties, delivery to the agreed place of destination is required.

Before making a device available on the market, the Buyer shall verify that all of the following requirements are met:

- The device has been CE marked and the EU declaration of conformity of the device has been drawn up.

- That the product is accompanied by a user manual and the characteristics label.

- That the manufacturer has assigned a unique identifier to the product.

For the fulfilment of these requirements the Buyer may apply a representative sampling method for the products supplied.

8. QUALITY

The Buyer who considers or has reason to believe that a product which he has made available on the market does not comply with Regulation 2017/746 shall immediately inform the manufacturer and, where applicable, its authorised representative and the importer. The Buyer shall cooperate with the manufacturer and, where applicable, its authorised representative and the importer, as well as the competent authorities to ensure that corrective action is taken to bring it into conformity, to withdraw it from the market or to recall it, as appropriate. If the Buyer considers or has reason to believe that the product presents a serious risk, he shall also immediately inform the competent authorities of the Member States in which he has placed the product on the market, providing details, in particular, of the non-compliance and of any corrective actions taken.

9. FIELD SAFETY CORRECTIVE ACTIONS AND RECALLS

Ortoalresa shall promptly (within twenty-four (24) hours) notify the Buyer in writing in the event that there are reasonable, suspected or proven indications that any lot or serial number of the Product is subject of a potential health or safety problem to the health of users or patients. Ortoalresa shall be solely responsible for establishing and submitting field safety notices and initiating Product recalls (field safety corrective actions) and instructing the Buyer to recall and return the Products. Ortoalresa will promptly notify the Buyer if Ortoalresa initiates a field safety notice (FSN) or a Product recall (field safety corrective action) in order to provide the Buyer with sufficient time to notify its customers.

Communication to regulatory authorities regarding Product recalls, recalls or field corrective actions will be coordinated by or through Ortoalresa.

Except as otherwise provided by law or as otherwise agreed, communication to customers regarding Product recalls, market withdrawals or field corrective actions shall be coordinated by or through the Buyer.

Ortoalresa agrees to provide the Buyer with the relevant FSN containing at least the information to enable it to properly inform its customers:

- Specific details to allow easy identification of the affected Products (e.g. type of device, description, model and reference number, lot/serial number of the affected devices and order number) and;

- Description of the problem and actions to be taken by the user (quarantine, recall, etc.).

The parties shall cooperate in the management and preparations for such product recall, market withdrawal or field compliance. In the event of disagreement, Ortoalresa shall have the final authority with respect to Product recall, recall or field corrective action, provided that in no event shall the Buyer's ability to comply with its legal and regulatory obligations arising from its decision on a Product problem requiring Product recall be limited.

The Buyer undertakes to inform Ortoalresa annually, throughout the life cycle of the Product, of:

- Any proposal for preventive action deemed necessary.
- Any option to improve the use, operation, and safety of the product.
- Any comments, complaints, or market experiences gathered in the field.
- Records concerning non-serious incidents.

This information may be communicated indirectly by the user to the Buyer and the latter to Ortoalresa.

The Buyer must also monitor any preventive and corrective actions initiated by the manufacturer.

10. REGULATORY REQUIREMENTS

Ortoalresa shall manufacture the Products in accordance with 2006/42/EEC, Medical Devices Regulation (EU) 2017/745 (MDR) and In Vitro Diagnostic Regulation (EU) 2017/746 (IVDR), as applicable and in accordance with the Regulations in force in the Territory.

If applicable, under local regulations in the Territory, the Buyer shall be responsible for submitting the necessary information or documentation to the various regulatory authorities solely in connection with Buyer's distribution or possession of Products. Ortoalresa shall provide all necessary documents, which may include, but are not limited to, certificates, labels and instructions for use, for the Buyer to submit. In the event of a request for additional information/documentation by a regulatory authority, the Buyer shall communicate the request to Ortoalresa who shall provide the necessary documents as soon as possible and always before the deadline.

11. STORAGE

In the event that Ortoalresa has communicated to the Buyer the availability of the Product to be picked up and the Buyer delays in the collection of the Product for a period of more than one month (1 month), Ortoalresa shall be entitled to invoice the Purchaser for storage costs of

50,00 euros per day (counted from the communication) in which the Product, being at the disposal of the Buyer, has remained in Ortoalresa's facilities.

Upon collection, the Buyer shall be held responsible for the Product and must ensure that the storage and/or transport conditions established by Ortoalresa are met.

12. TRANSFER OF RISKS

All the Products are at the risk of the Buyer from the moment they are handed over to the Buyer or to the Buyer's Transport Company.

All the Products shall remain the property of Ortoalresa, which reserves its ownership, until all the accounts owed by the Buyer to Ortoalresa have been settled and the amounts corresponding to the invoices have been paid.

Payment shall be considered due at once and automatically at the beginning of any act or procedure in which the Buyer's insolvency is involved.

In the event that, once the payment is due and has not been paid by the Purchaser to Ortoalresa, the Purchaser has sold the Product or part of it to a third party, it shall be understood that such sale has been made acting as Ortoalresa's fiduciary agent.

The Buyer shall conduct the procedures of such sale on behalf of Ortoalresa and shall account for such actions in a separate account, at once crediting the amount obtained from the sale to Ortoalresa.

13. RESERVATION OF TITLE

Ortoalresa will continue to keep ownership of the Products delivered to the Buyer until such time as full payment of the purchase order price and other amounts owed by the Buyer because of the purchase has been made.

Until such time, the Buyer is obliged to inform Ortoalresa in writing as soon as possible of any third-party intervention in the delivered Products, possible damage or any other circumstances that may affect the Products.

If the reservation of ownership contemplated here exists, the sale, pledging or any type of transfer of the Product shall not be admissible unless expressly accepted by Ortoalresa.

In the event of resale, the price received by the Buyer must be recorded as assigned to Ortoalresa and the Buyer may inform the third-party Buyer of such assignment. Likewise, the Buyer assumes the obligation to record this in its books and invoices.

Ortoalresa reserves the right to collect the price from the third-party Buyer of the Product when the Buyer does not comply punctually with its payment obligations.

14. CLAIMS REGARDING THE PRODUCTS

Regarding the deliveries made by Ortoalresa under EXW Conditions, Incoterms 2020 of the International Chamber of Commerce, where the effective delivery shall be understood to have taken place at the moment of the Products being handed over to the Buyer or to the Buyer's Transport Company, the deadlines for making a claim shall be those contained in the following paragraphs:

The Buyer shall examine the Products, as soon as possible after receipt, to verify their conformity with the type of Product ordered, and the absence of apparent or hidden defects in them. Nonetheless, after receiving the Products, the Buyer will have a period of 5 days to submit a claim to Ortoalresa for a difference in type between the Products delivered and those ordered or for the existence of an apparent defect in them. If the Buyer detects a possible internal or non-apparent defect in the Products, the period available to submit a claim to Ortoalresa will be 30 days after receipt.

If the Buyer considers or has reason to believe that the Product presents a serious risk or is counterfeit, he shall notify the Competent Authority of the Member State in which he is established and provide all available information and documentation. Similarly, he shall collaborate with the Competent Authority to provide free samples of the Product, or when not possible, grant access to the Product.

With regard to the cases contained in paragraphs 7 and 8 of Point 2 in which, depending on the amount of the purchase order or the particular agreements between the parties, delivery must be made to the agreed destination and therefore Ortoalresa has sent the Products through the Transport Company contracted by the same, the recipient of the Product shall have a period of 24 hours from receipt of the Product to notify Ortoalresa of a possible defect in quantity or a visible defect in the packaging.

The Buyer's conformity shall be obtained by signing the corresponding delivery note at the same time of delivery. If the buyer does not submit his claim within the indicated period of 24 hours, Ortoalresa will not assume any responsibility whatsoever.

Ortoalresa will not accept any claims received after the expiry of the aforementioned periods. If the Buyer's claim is justified and received on time, Ortoalresa will have the sole and exclusive obligation to replace the defective Products with substitute Products and shall not be liable for any loss or damage which may arise for the Buyer as a result of delay or non-delivery of conforming Products, in particular loss of profit, loss of production or loss of benefit, in accordance with the provisions of Condition 12 below.

Buyers who have received complaints or reports from healthcare professionals, patients, or users regarding alleged incidents related to a product they have commercialized, shall immediately transmit this information to the manufacturer and, if applicable, to their authorized representative

and the importer. Similarly, Buyers shall keep a record of the complaints, non-conforming products, and product recoveries and recalls, and shall keep the manufacturer and, if applicable, the authorized representative and the importer informed of such monitoring, providing them with any requested information.

15. LIMITATION OF LIABILITY

The Buyer is solely responsible for the choice of the Product bought, as well as for the use or function for which it is intended. Consequently, Ortoalresa is not responsible for and does not guarantee that the Product is suitable for the technical applications intended by the Buyer, nor for achieving, in whole or in part, the aims foreseen by the Buyer when buying the Products. In this respect, the Buyer shall not be entitled to return the Products and claim the price paid.

Any technical advice provided by Ortoalresa verbally, in writing or by tests, before and/or during the use of the Product, is provided in good faith, but without guarantee.

Ortoalresa's advice does not release the Buyer from its obligation to evaluate the Product supplied to decide its suitability for the processes and uses for which it is intended.

Except for when intentional conduct or gross negligence is found, Ortoalresa shall in no event be liable for any damages suffered by the Buyer. Furthermore, any liability for indirect damages, consequential damages, non-material damages, business or environmental damages, loss of profit, loss of goodwill, or damages because of liability to third parties, is excluded.

In any case, should Ortoalresa be obliged to assume liability for damages suffered by the Buyer, such liability shall be limited to an amount equivalent to the corresponding amount appearing in the order confirmation for the Product causing the damage, unless an applicable mandatory law imposes a higher quantitative limit on Ortoalresa.

The Buyer shall be solely liable, exonerating Ortoalresa as appropriate, for any damage arising against its own employees or third parties due to improper use, storage, conservation, handling or transformation of the Products, in particular, but not limited to, when the Buyer has not observed the indications, warnings or instructions that Ortoalresa may have provided in this regard in the technical documentation provided with the Product.

Ortoalresa shall under no circumstances be liable to third parties for causes beyond its control, including non-compliance by the Buyer with the regulations applicable to the Products and chemical substances. The Buyer shall hold Ortoalresa harmless from any liability for any claims, damages and/or losses arising, directly or indirectly, from the non-fulfilment of the obligations assumed by the Buyer by virtue of their contractual relationship.

16. INSTALLATION AND COMMISSIONING

The installation of the equipment shall in all cases be the responsibility of the Buyer, who must ensure that the products had been installed correctly and safely, in accordance with the manufacturer's installation instructions, which may be previously requested from Ortoalresa, following the guidelines of good commercial practice, without risk to the health or safety of persons. Ortoalresa is not responsible for the Buyer's failure to comply with this clause.

17. WARRANTY AND RETURNS

The Products have a warranty from the manufacturer as stipulated for each Product, being 24 months from the date of invoice for the Products and 6 months from the date of invoice for spare parts or any type of service or repair, for which the date contained in the delivery note of these will be considered. Please check the General Conditions of Warranty on the web: www.ortoalresa.com.

If the Buyer detects defective Products, he must notify Ortoalresa at once and in writing, specifying at least the serial or batch number of the Product and a brief description of the defect.

After being previously authorized by Ortoalresa, any return must be made in the original packaging material and with any accessories, documentation, computer media, etc. included with the product, even if it is defective.

Once verified by Ortoalresa that there are defective Products (whether materials or services), it will proceed in accordance with the provisions of the General Conditions of Warranty on the website: www.ortoalresa.com.

After the examination of the returned Product, if it is found that it is working correctly or that the cause of the malfunction is unrelated to the Product itself, it will be returned to the Buyer with postage due, together with a charge for the duration of the intervention of the technical service for handling and verification.

The cost of sending the product to Ortoalresa's technical service will be charged to the Buyer.

Products or parts of a product that have been substituted or repaired under warranty will be guaranteed only for the remaining unexpired period of the original warranty applicable to the specific Product.

18. SERVICE CONDITIONS

All the provisions contained in these GTC shall also apply to all repairs, maintenance, inspections, or other types of services that had been specifically ordered by the Buyer to Ortoalresa.

19. OBLIGATION OF ELIMINATION

Once the use period has ended, the Buyer assumes the obligation to treat and dispose of the Product supplied by its own means and following the legal provisions in force. Furthermore, the Buyer expressly releases Ortoalresa from its obligations under art.10 paragraph 2 of the German Electrical Equipment Act (obligation to return to the manufacturer) and the rights of third parties arising therefrom. Ortoalresa's right to take over/exemption by the Buyer shall expire no earlier than two years after the final termination of the operation and the written notification to Ortoalresa. At the express request of the Buyer, Ortoalresa may organize the return and reuse/disposal of the Product against reimbursement of the incurred costs, provided that the Product has been manufactured by Ortoalresa.

20. DATA PROTECTION AND CONFIDENTIALITY

Ortoalresa is the Controller of the Buyer's personal data and informs you that these data will be processed following the provisions of the regulations in force, Regulation (EU)2016/679 of 27 April 2016 (GDPR), and therefore the following processing information is provided to you:

Purpose of processing: Provision of the requested service, administration, and communication management of the company.

Data retention criteria: Data will be kept for as long as there is a mutual interest in maintaining the purpose of the processing and when it is no longer necessary for that purpose, it will be deleted with appropriate security measures to ensure the pseudonymization of the data or the destruction of the data.

Communication of data: Data will not be communicated to third parties, unless legally obliged to do so.

Rights of the data subject: - The right to withdraw consent at any time. - Right of access, rectification, portability, and deletion of their data and to limit or oppose its processing. - The right to submit a complaint with the supervisory authority (agpd.es) if he/she considers that the processing does not comply with the regulations in force.

Contact details to exercise your rights:

Identity: ALVAREZ REDONDO, S.A.

CIF/VAT: ESA 78757903

Postal address: C/Los Frailes 121, Pol. Ind. Los Frailes, 28814 Daganzo (Madrid).

Telephone: +34 918844016

E-mail: info@ortoalresa.com

21. INTELLECTUAL PROPERTY RIGHTS OF THIRD PARTIES

Ortoalresa shall not be liable for the breach by the Buyer of intellectual property rights, for an unforeseeable use of the Products sold, for the fact that the Buyer changes the shipment or uses it together with other Products or consumables not supplied by Ortoalresa.

The documentation delivered with the Products or services will always be the property of Ortoalresa and must not be disclosed to third parties unless this is legally required or with prior authorization from Ortoalresa.

22. FORCE MAJEURE

Ortoalresa will not be liable for the non-fulfilment or delay in the fulfilment of its obligations to the Buyer, if this is caused by any fortuitous event or force majeure affecting both Ortoalresa and its suppliers or carriers, including strikes, other labor, or industrial contingencies, lack or impossibility of obtaining raw materials, etc. If the cause of force majeure is extended for more than 2 months, Ortoalresa or the Buyer may consider that the orders for Products in progress shall be cancelled without giving rise to any indemnity or compensation for the Buyer.

23. APPLICABLE LAW AND JURISDICTION

The contractual relations between Ortoalresa and the Buyer, object of the present GTC, will be governed exclusively by Spanish Law, with the exclusion of the Vienna Convention on the International Sale of Goods of 1980.

Any disputes in connection with Ortoalresa's business relations with the Buyer shall be decided with express renunciation of any other Authority that could correspond to them, to the exclusive jurisdiction of the Courts of the city of Madrid. Nevertheless, in case of non-fulfilment by the Buyer of any payment obligations derived from the present GTC, Ortoalresa may choose alternatively, to exercise the legal actions that belongs to it at the Courts of the place where the Buyer's address is found.

Date: 08/02/2024

Approval: Penélope Álvarez



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ÁLVAREZ REDONDO, S.A.