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Medisol - Dealer Business Relations Cooperation Agreement

Professional Products

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HZ UNIVERSITY - INTERNATIONAL BUSINESS

Contents

Introduction

This document contains the professional products developed as a result of carrying out a research at Medisol, one of the leading suppliers of automatic external distributors and related products in Europe. The aim was to come up with an agreement that will help Medisol to meet the new Medical Devices Regulation (MDR) requirements as well as help the company retain loyalty of its dealers.

From the research findings, it turned out that it is appropriate to use a commercial agreement mainly outlining the purchase and supply terms and conditions to aid loyalty and a Quality Agreement to aid in meeting the MDR requirements. Three Quality Agreements were recommended basing on the MDR economic Operator role Medisol can assume in relation to its dealers (Distributors in the MDR language). However, time allowed to develop only one.

Below the SAFe criteria is use to underpin the these professional products.

SAFe - Commercial cooperation agreement

Suitability	Basing the agreement on relational norms something also in line with the values at Medisol shall make the agreement attractive for dealers to sign hence can give a competitive advantage to Medisol.
Acceptability	Since the company has a goal of professionalization, the agreement with purchase and supply conditions stated in advance for all dealers will help achieve this. When conditions are flexible and lead to trust building relationships with dealers, it will lead to customer loyalty and increased revenue for the company.
Feasibility	Drafting this agreement shall not need external expertise. The researcher has produced a concept which can be fine-tuned especially with the help of the marketing expertise already available at Medisol in the marketing department. Therefore, practically achievable without any extra financial investments needed.

Suitability	The new MDR regulation will change the business operations in the Medical devices industry significantly. Nonconformity for devices Medisol supplies to its dealers will have legal consequences in case roles are not properly defined. Therefore, the quality agreement developed as a result of this research in accordance with the MDR requirements can be used as a tool against legal consequences. Since the objective of Medisol is getting a CE certificate to keep its products on the EU market, these agreements will aid in this.
Acceptability	Without an agreement which clearly outlines responsibilities for Medisol and the dealers in line with the economic operator roles as defined in the MDR, the company can risk losing access to the EU market in such cases that the dealer does not effectively fulfil its MDR roles. To meet its short term and long term objectives of increased sales through selling on the EU market and avoid negative impact on its already good brand image, it is recommended that the company works with these agreements. This is a new system which would need consideration. https://youtu.be/O1Ol3udZeII
Feasibility	It would not require financial investments to produce this agreement through hiring external specialists for example. The company has a business development team with skills to come up with the quality agreements. The researcher has produced a concept which can only be modified. Therefore, practically achievable.

Professional Product 1 – Commercial cooperation agreement

COOPERATION AGREEMENT FOR THE PURCHASE & SUPPLY OF GOODS[1]

This cooperation agreement is a reflection of the beliefs and behaviours Medisol and company (x) have in their collaboration to achieve joint and individual goals. Being a dealer for Medisol comes with the following priveleges among others; You will be:

- Able to Sell under your own company name.
- Able to benefit from Competitive prices.
- Able to acquire a wide range of manikins, including leading brands such as Ambu and Laerdal in addition to the AED's.
- Assured of stock availability most of the time
- Able to Receive quick and On time tracked delivery of goods
- In position to benefit from an effective, efficient and affordable service (maintanance) contract for AED's that Medisol offers
- Able to get Expert and independent advice from proffesionals at Medisol about products and serives as well as recent developments in the industry.
- Able to have deliveries made directly to your customer on your behalf.

That said, both companies agree to cooperate in the success of this agreement by meeting or exceeding all requirements and guidelines defined in this document.

Commencement & Periodic Review

Upon approval and signing of this agreement, Medisol the Dealer shall receive a dealer account from which products and their respective prices can be accessed.

This agreement is just a starting point and shall be adapted as the market, exchange relationship, and the fortunes of both companies develop. Therefore, every after (x months), it shall be evaluated by both companies to discover areas to improve.

Purchase Orders

As a dealer for Medisol, you are not bound to order a fixed amount within a certain period unless there is a special arrangement made for this in writing and signed by both companies in addition to this agreement.

The prices for the goods shall be those as shown in the dealer account.

There will always be an opportunity to get discounted prices when a large order is placed.

[1] Only applicable for EU dealers since that was the scope of my research

Dealer shall be requested to place orders through the following ways; (1) Most preferably through the web shop from dealer account or (2) by e-mail in case this is inevitable. Ordering via the web shop will not only save time and administration costs but also earn the dealer loyalty points. These can be used to get discounts on products or buy a product if they accumulate to such an amount sufficient to do so.

Medisol promises to honor the warranties and guarantees at all times as they appear in the web shop for the products and services.

Delivery

Delivery arranged by Medisol shall be via UPS which usually takes 2-3 working days from dispatch and shall bear full responsibility until the point when goods are delivered to the desired destination address. Dealer shall receive a tracking code to monitor the delivery progress and shall receive timely updates about the order status in case of any changes in previously communicated details.

Orders with a value of [2](amount) and above will not be charged a surcharge fee to be delivered. When the order value is less than (amount), Dealer shall be requested to pay a surcharge fee of (amount) on top of the order amount for deliveries arranged by Medisol.

Medisol accords its dealers also the possibility to organize own delivery. In that case, it shall bear responsibility until the point when goods are dispatched from its premises.

Delivery shall be made to the delivery address on the proforma invoice. In case it is the wish of the Dealer to have goods delivered to its customers by Medisol, this shall be made in neutral packaging and with a neutral packing list without any Medisol labels.

In case the goods delivered do not comply with the order, Dealer has the right to reject and return the goods and the order. Dealer shall in that case inform Medisol immediately about the matter to arrange collection of the items. These will then be replaced and re-sent or money refunded depending on what has been agreed upon.

[2] This can be challenging as salespersons were of the view that this remains as it is. In my view, I think it would be better to discuss with them first before making any changes for current dealers. Could be implemented for new dealers in my opinion with room for adjustment as the relationship progresses.

Payment

Dealer shall be requested to make payments using one of the following means: (1) a bank transfer on the Medisol account number stated on the Proforma invoice, (2) PayPal, (3) ideal and (4) Credit card.

At the start of the cooperation, Dealer shall be requested to pay for the first (x) orders in advance. Thereafter, there will be a possibility to discuss future business arrangements among which payment after the goods have been delivered. Any agreement reached shall be confirmed via mail.

In such cases when outstanding amounts for goods received on credit is not received within a period as agreed above, two reminders shall be sent. It is therefore expected that Dealer communicates with Medisol upon receipt of the reminders to enable continued processing of goods.

Dealer is further encouraged to endeavor to pay within the agreed time frame to avoid such unwanted outcomes like a reduction in the credit amount Medisol can advance among others.

Up to an equivalent of (x) euros can be advanced on credit at any given time. However, during the review of the cooperation, there is an opportunity to discuss this further

VAT charged on Goods

VAT of (x%) shall be charged on the total cost of goods. Dealers with a valid VAT number shall be charged no VAT.

Harmonizing misunderstandings

Both companies shall always endeavor to work out a collective solution in case of a disagreement. It is therefore hoped that this shall at all times lead to a positive result to avoid involvement of third parties among which the Dutch courts of law.

Revision of the agreement

Should there need arise requiring this agreement to be modified , this shall be done in writing and signed by both Medisol and the dealer representatives.

Compliance with EU MDR[3]

In addition to this agreement, both companies shall be required to sign a Quality Agreement agreeing to cooperate towards achieving the MDR responsibilities stated in it**.**

SIGNATURES

Medisol and (company x) have agreed to enter into this cooperation agreement by their duly authorized representatives as of the effective date written below.

(day) of (month) (year)

Medisol B.V.:	[Company]:
By: _____	By: _____
Name:	Name:
Title:	Title:

[3] Only for dealers in products under the MDR. Section can be left out for other dealers. The quality agreement shall be based on the relationship between Medisol and the dealer in question *as defined in the MDR ; Manufacturer – Distributor., Importer – distributor. Or AR –. distributor*

Professional product 2 – Quality Agreement

Regulatory and Quality Agreement

-Division of Responsibilities –

This cooperation Regulatory and Quality Agreement outlines the division of responsibilities between Medisol and Company (X) in accordance with the requirements of the EU MDR 2017/745. At some points in this document Medisol shall be identified as "Company" whereas Company (X) as "Distributor". Both Medisol and Company (X) shall together and individually be referred to as the "Party" or "Parties".

In this relationship, Medisol shall assume the role of the Manufacturer according to the EU MDR 2017/745 whereas company (x) the role of the Distributor. This agreement is made purposely for the distribution of the Defisign AED.

The parties agree that:

Subject of the Agreement

Subject of the agreement is the Defisign Life AED to be further referred to as the " product" at some points. Details specified in **Annex 1** of the agreement. The parties agree to meet the requirements regarding development, manufacturing, quality assurance, documentation, conformity assessment and vigilance on basis of the legal requirements for manufacturing and distribution of medical devices as laid down under the EU Medical Device Regulation MDR EU 2017/745.

The **Annex 2** of this agreement provides a definition of responsibilities which governs the demarcation of the mutual responsibilities of the parties in detail. In the absence of regulation in **Annex 2** to this agreement, the responsibility remains with Medisol.

Price agreements and other contractual exchanges of benefits (in particular, but not exclusively, delivery, delivery time, delay of delivery, risk taking, warranty, intellectual property, distribution etc.), are subject to a separate and independent agreement between the parties as long as this contract does not contain explicit provisions. The effectiveness of this agreement will not affect the existence of such additional agreement.

Term and Ending cooperation

The contract shall commence upon signature by both parties and expires after (X months) if one of the parties ends the cooperation by written notice within a period of (X days) before the expiry date. The term of the agreement is extended continuously by (X weeks), if not previously ended.

The right to end the cooperation for good causes remains unaffected.

Furthermore, in the case of insolvency of either of the parties, the cooperation agreement may be discontinued with immediate effect.

Duties of Medisol

In the following the basic duties of Medisol are highlighted whereby the details can be found in **Annex 2**:

Among these are in particular the control and maintenance of product specifications, the auditing of Distributor activities, the manufacturing of the Product according to approved specifications, the implementation and maintenance of a quality management system including the implementation of conformity assessment procedures, the maintenance of a product technical file, and the preparation and maintenance of documentation for proper inspection by the competent authorities.

Regulatory Provisions for Medisol

Medisol guarantees that the Defisign Life AED complies with the requirements of Annex I of Medical Device Regulation MDR EU 2017/745. It will submit an EC declaration of conformity according to Annex IV of EU Medical Device Regulation MDR EU 2017/745 and will provide the Defisign Life AED with a CE-mark for a proper marketing in [Country X].

In addition, Medisol maintains a quality management system certified to ISO 13485:2016 and a quality assurance system in accordance with Annex IX EU Medical Device Regulation MDR EU 2017/745. An up-to-date version of the quality dossier will be available at request of Distributor in the current version.

It also has appointed a person responsible for regulatory compliance (Safety Officer) in accordance with Article 15, Medical Device Regulation MDR (EU) 2017/745.

Regulatory Provisions for Distributor

Medisol acknowledges the *General Obligations of Distributors,* noted in MDR (EU) 2017/745, Article 14. Further, it agrees to provide any required information and to support the Distributor to meet its MDR 2017/745 distributor obligations. The Distributor obligations include the following:

1) Before making a Defisign Life AED available on the market, the Distributor must verify that all of the following requirements are met:

(a) the Product has been CE marked and that the EU declaration of conformity of the device has been drawn up;

(b) the Product is accompanied by the information to be supplied by the Company in accordance with Article 10(11); and

(c) a UDI has been assigned by the Company.

(d) In order to meet the requirements referred to in points (a), (b) and (c) above, the Distributor may apply a sampling method that is representative of the Defisign Life AED's supplied.

2) Where Distributor considers, or has reason to believe, that a Product is not in conformity with the requirements of MDR (EU) 2017/745, it shall not make the Product available on the market until it has been brought into conformity, and shall inform Medisol. Where the Distributor considers, or has reason to believe, that the Product presents a serious risk or is a falsified device, it shall also inform the competent authority of the Member State in which it is established

3) The Distributor shall ensure that, while Product is under their responsibility, storage or transport conditions comply with the conditions set by the Company. The Distributor must also engage in Post-Market Surveillance (i.e., report complaints, feedback).

4) Where the Distributor considers, or has reason to believe, that a Product which they have made available on the market is not in conformity with MDR (EU) 2017/745, the Distributor shall immediately inform Medisol. The Distributor shall co-operate with the Company and with competent authorities to ensure that the necessary corrective action to bring the Product into conformity, to withdraw or to recall it as appropriate, is taken. Where the Distributor considers, or has reason to believe, that the Product presents a serious risk, it shall also immediately inform the competent authorities of the Member States in which it made the device available, giving details of the noncompliance and of any corrective action taken.

5) When the Distributor receives complaints or reports from healthcare professionals, patients or users about suspected incidents related to a Product they have made available shall immediately forward this information to Medisol. The Distributor shall keep a register of complaints of non-conforming devices and of recalls and withdrawals, and keep Medisol informed of such monitoring and provide it with any information upon request.

6) The Distributor shall, upon request by a competent authority, provide them with all the information and documentation that is at their disposal and is necessary to demonstrate the conformity of a Product.

7) The Distributor shall be considered to have fulfilled the obligation referred to in the first subparagraph when Medisol provides the required information. The Distributor shall cooperate with competent authorities at their request on any action taken to eliminate the risks posed by Product which they have made available on the market. The Distributor, upon request by a competent authority, shall provide free samples of the Product or where that is impracticable, grant access to the Product.

Production

Medisol undertakes to manufacture the Defisign Life AED in accordance with ISO 13485:2016, section 7 and the documentation listed in **Annex 2** of this agreement.

In addition, it is solely responsible for the fulfilment of duties in relation to Distributor, also in the event of subcontracting third parties. Medisol will take responsibility for the performance provided by the subcontracted third parties in regard to this agreement and in particular in regard to the compliance with the respective quality management standards. Company will subcontract third parties by written manufacturing contracts only.

Technical Documentation

Medisol prepares and maintains technical files with all relevant product information. Distributor creates and provides quality documents, in accordance with the QMS, required by Medisol in the current version available (more details can be found in **Annex 2**).

Training

Medisol is responsible for developing training materials to train medical consultants so that these can adequately instruct customers in the use of the Defisign Life AED.

Duties of distributor

The basic duties of Distributor, in addition to those noted in Section Technical documentation above of this agreement, are defined below. Further details can be found in **Annex 2**.

The essential duties of Distributor is the distribution, in accordance with the QMS of Medisol, of the Defisign Life AED.

Product Specifications

Medisol is responsible for the development and maintenance of the Defisign Life AED specifications, under control of and in accordance with its QMS. Distributor may submit suggested changes to product specifications to Medisol relating to the manufacture of the Product

Packaging and labelling

Distributor is responsible for the creation of packaging and labelling specifications, under control of and in accordance with the QMS of Medisol, for the Product under respect of EU Medical Device Regulation MDR EU 2017/745. Medisol is responsible for approving any such labelling and for applying and including Distributor labels to products they package. The labelling of the Product will state the following notice:

"Manufactured by [Medisol B.V./Schiller Medical] and "Distributed by [Distributor Name].

Quality issues/complaints

Medisol is responsible for processing customer complaints, conducting complaint investigations and for post market surveillance (PMS) of Product . Distributor is required to support Company's complaint handling system and PMS activities.

When the Distributor receives complaints or reports from healthcare professionals, patients or users about suspected incidents related to a Product they have made available the Distributor shall immediately forward this information to the Medisol .The Distributor shall keep a register of complaints of non-conforming devices and of recalls and withdrawals, and keep the Company informed of such monitoring and provide it with any information upon their request.

Distributor is responsible for developing and maintaining a procedure(s) for the acceptance of goods and quality control of the Product manufactured by Medisol. Distributor is required to examine the Defisign AED and its technical documentation and to notify Medisol in writing about any defects of the Product, giving a detailed description of the defects. The same applies to deficiencies in the documentation of the Product and to defects that only become noticeable during the storage or further processing of the product, after marketing of the product or by notice of a third party.

If Distributor rejects a product, it is obliged to return the respective item to Company immediately.

Distribution

Distributor is responsible for the distribution of the Product in [Country X]. Distributor undertakes to promote the Product in the territory at its own expense and in an appropriate extent. Distributor will discuss with Medisol any intended marketing measures always prior to carrying out any such measures.

Medical device Vigilance

Company is responsible for the medical devices vigilance. Company has to decide when an event is an "incident" as defined in Article 2, Medical Device Regulation MDR (EU) 2017/745 and will be responsible for the reporting of incidents. Company and the appointed safety officer of Company are responsible for the observance of the notification period required by the competent higher federal authorities. In the course of such process, Company will evaluate the incident and the implementation of corrective measures. This includes the coordination of measures with the competent authorities and their final implementation. Company will include Distributor in an advisory capacity when deciding on the nature and extent of the corrective measures.

Company is responsible for the technical verification and the internal tracking of defects on the Contractual Product. Company informs Distributor about any implemented measures which serve the prevention of further defects on a regular basis.

Distributor is obliged to fully cooperate and assess any incidents. Distributor has the obligation to inform Company about any events immediately or latest within a period of 1 working days. This includes incidents that Distributor became aware of by itself or was informed by a third party and which might have any effect on the Contractual Product. Distributor has to maintain a constantly updated documentation of incidents.

Traceability

Medisol shall have established a written procedure on traceability and Unique Device Identification (UDI) in accordance with ISO 13485:2016. The extent of traceability as well as the required documentation must be defined in the procedure. The Distributor shall cooperate with the Company to achieve an appropriate level of traceability of the product.

The Company and Distributor shall ensure the ability to identify:
(a) any economic operator to whom they have supplied a device;
(b) any economic operator whom had directly supplied them with the product;
(c) and any health institution or healthcare professional to which they have directly supplied a contractual product.

Change Management

Distributor and Company are both committed to maintain a functioning change management system.

Medisol informs Distributor about any changes in regard to the manufacturing process and testing of the Product.

Distributor is obliged to notify Company about any changes in the product labelling or packaging of the Product. Any such changes will be under the control of and in accordance with Company's QMS. Medisol will be responsible for all decisions on the implementation of the planned product and any packaging changes. A respective change shall not be released without the prior consent of Company.

Company is responsible for the quality assessment of changes, including validation when applicable, adaptation of the technical documentation and the notification duties to competent authorities arising on this. Distributor agrees to provide adequate support to Company for these activities.

Mutual information requirements

The Parties shall inform each other immediately on any recalls or customer complaints which they are informed about, as well as on authority complaints which are directly or indirectly related to the Contractual Product and/or its packaging material.

Where the Distributor considers, or has reason to believe, that a product which they have made available on the market is not in conformity with MDR (EU) 2017/745, the Distributor shall immediately inform Medisol . The Distributor shall co-operate with the Company and with competent authorities to ensure that the necessary corrective action to bring the product into conformity, to withdraw or to recall it as appropriate, is taken. Where the Distributor considers, or has reason to believe, that the product presents a serious risk, it shall also immediately inform the competent authorities of the Member States in which it made the device available, giving details of the noncompliance and of any corrective action taken.

Competent contact Persons

The Parties have appointed responsible contact person for each area of responsibility as listed in Annex 2 of this Agreement. These appointments are made to simplify communication arising from this agreement and is independent of the definition of responsibilities in Annex 2 to this agreement.

The Parties will inform each other immediately in writing in case of appointment of a new person as the contact person.

These contact persons are authorized to make or accept any declarations under this agreement.

Inspections and Audits

Medisol gives unrestricted access to its premises to the competent notified bodies for audit purposes and provides for complete documentation of the Product. It will provide this information or copies of the respective technical files on request for inspection.

Medisol also ensures respective rights of access and inspection at the site of any of its sub Distributors.

Distributor agrees to give unrestricted access to its premises to Medisol, notified bodies and competent authorities to ensure Distributor activity relating to the Product comply with Company's Quality Management System, applicable standards and regulations.

Record Keeping

The parties shall manage and store all documents arising within the framework of this agreement or which are necessary to carry out this agreement for a period of 10 years from the expiry date of the Product and shall make them available to the other Party upon request.

Secrecy

The Confidential Information of a Party (the "disclosing party") which is disclosed to the other Party (the "receiving party") will be held strictly confidential by the receiving party at all times and not be used by the receiving party (or its affiliates, employees, officers, directors or limited liability company managers and agents for any purpose not previously authorized by the disclosing party. The Confidential Information of the disclosing party will not be disclosed or revealed by the receiving party to anyone, except as required by law or regulation, or with the prior written permission of the disclosing party and on the condition that the party to whom the Confidential Information is disclosed agrees in advance and in writing to be bound by these terms and conditions. The receiving party may disclose the Confidential Information to those of its employees or advisors who need to review the Confidential Information for the purposes authorized by the disclosing party, but only after having informed them of the confidential nature of the Confidential Information and after communication on how this Confidential Information needs to be treated according to this agreement. The disclosing party retains all rights, titles and interest in and to its Confidential Information.

The term "Confidential Information" includes, but is not limited to, any information of either the receiving or disclosing party (whether oral, written, visual or fixed in any tangible medium of expression), relating to either party's services and "know-how" but does not include information which (i) is or becomes generally available to the public other than as a result of disclosure by the receiving party, (ii) was known to the receiving party before it was disclosed to the receiving party by the disclosing party, (iii) was or becomes available to the receiving party from a source other than the disclosing party, provided such fact is evidenced in writing and the source is not bound by a confidentiality obligation to the disclosing party.

Upon the earlier (i) expiration or ending of this Agreement or upon (ii) the request of the other Party, the party will return to each other all confidential and proprietary information in its possession in a manner mutually agreed upon by the parties.

The confidentiality obligation does not apply in case that legal requirements make it necessary to submit information to third parties as in particular public authorities. At

submission of documents due to a request of the competent authorities, the submitting Party clearly needs to inform upon the confidential nature of the documents and ask to treat them as trade and business secrets, as well as immediately inform the other Party upon the request for and/or the submission of documents.

Succession

The regulations of this agreement will be passed on to a legal successor as far as the legal and agreement requirements are met. Otherwise, there will be a mutual right to ending of this agreement.

Modification of agreement

Any changes in or additions to this agreement shall be in writing.

Authority and applicable law

The agreement is subject to the Dutch law.

Miscellaneous

If any provision of this agreement becomes invalid or unenforceable, this shall not affect the validity of the agreement as a whole. The Parties agree to include a valid or enforceable provision in place of the invalid or unenforceable one, which meets the spirit and purpose of the original provision as closely as possible; the same applies to possible gaps in the agreement.

Claims under this agreement cannot be assigned to any third Parties without the written consent of the other Party.

Medisol and Distributor have agreed to enter into this Regulatory cooperation agreement by their duly authorized representatives as of the effective date written below.

[Medisol B.V.].:

By: _____

Name:
Title:

[Distributor]:

By: _____

Name:
Title:

ANNEX 1 - Defisign CODES AND DESCRIPTIONS/SPECFICATIONS

ANNEX 2
RESPONSIBILITIES [EXAMPLE ONLY- MODIFY AS NECESSARY]

QUALITY SYSTEM

ITEM	MEDISOL	DISTRIBUTOR
1. ISO 13485:2016 Certification	**Responsible**	-
2. FDA QSR Compliant	**Responsible**	**Responsible**
3. Notification If Certification Is Suspended or Withdrawn	**Responsible**	-
4. Complaint Handling System	**Responsible**	**Contributor**
5. Medical Device Reporting	**Responsible**	**Contributor**
6. Remedial Action / Recall	**Responsible**	**Contributor**
7. Post Market Surveillance	**Responsible**	**Contributor**
8. Corrective and Preventive Action	**Responsible**	**Responsible***
9. Non-Conforming Material	**Responsible**	**Responsible***

*** Distributor receipt / storage / distribution of contractual product**

MANUFACTURING PROCESS

ITEM	MEDISOL	DISTRIBUTOR
10. Manufacturing Documentation (DMR)	**Responsible**	-
11. Manufacturing Drawings	**Responsible**	-
12. Manufacturing Work Instructions	**Responsible**	-
13. Bill of Materials / Routers	**Responsible**	**Contributor**
14. Sterilization Validations	**Responsible**	**Contributor**
15. Traceability (Raw Materials and Finished Product)	**Responsible**	**Contributor**
16. Create and Revise CNC Programs	**Responsible**	-
17. Special processes certifications according to ISO 11135/11137 (if applicable)	**Approval Required**	**Responsible**
18. In-process / final inspection plans	**Responsible**	**Contributor**
19. First article inspections	**Responsible**	-
20. Sterile product lot release (if applicable)	-	**Responsible**

PACKAGING / LABELING

ITEM	MEDISOL	DISTRIBUTOR
21. Packaging Process Development and Validation	**Approval Required**	**Responsible**
22. Application of Company Approved Labeling to Product	-	**Responsible**
23. Inclusion of Instruction for Use with Product	-	**Responsible**
24. Release & update label content	**Responsible**	**Contributor**

CUSTOMER SERVICE

ITEM	MEDISOL	DISTRIBUTOR
Who carries out customer service	**Responsible**	-
Responsibility for customer service and its quality	**Responsible**	-

FINISHED LOT DOCUMENTATION

ITEM	MEDISOL	DISTRIBUTOR
1. Certificates of compliance (material and production)	**Keep Original**	**Copy Upon Request**
2. Test/Inspection Results	**Keep Original**	**Copy Upon Request**
3. Sterile product lot release (If Applicable)	**Copy Upon Request**	**Keep original**
4. Device History Record (DHR)	**Copy Upon Request**	**Keep original**

AUTHORIZED SUBCONTRACTORS

SUBCONTRACTOR	RESPONSIBILITY
Company 1 [Name and Address] Company 2 [Name and Address] Company 3 [Name and Address]	