

INTERNATIONAL NON-EXCLUSIVE DISTRIBUTION AGREEMENT

This International Non-Exclusive Distribution Agreement ("Agreement") is made and entered into as of 10th October, 2021 ("Effective Date") between TIDI Products, LLC, a Delaware, United States limited liability company with its principal place of business at 570 Enterprise Drive, Neenah, WI 54956 ("TIDI") and VIAMED LTD, with a principal place of business at 15 Station Road, Cross Hills, Keighley BD20 7DT, United Kingdom ("Distributor").

RECITALS

WHEREAS, TIDI is engaged in the business of developing and selling innovative products in the healthcare industry that provide caregiver support and safety, patient protection and improved outcomes; and

WHEREAS, TIDI and Distributor desire that Distributor be authorized to act as an independent distributor for the TIDI Products in the Territory (as defined below), only under the terms and conditions set forth herein;

NOW THEREFORE, in consideration of the mutual promises and covenants contained in this Agreement, and other good and valuable consideration, the parties hereto have agreed and do hereby agree as follows:

AGREEMENT

1. APPOINTMENT AS AUTHORIZED DISTRIBUTOR

- 1.1. Non-Exclusive Appointment. Subject to the terms and conditions of this Agreement, TIDI appoints Distributor, and Distributor accepts such appointment, as an independent, ~~exclusive~~ distributor of the products set forth on the attached Exhibit A ("TIDI Products"), in and limited to the territory set forth on the attached Exhibit B incorporated herein by reference (the "Territory"). The Distributor shall refrain from making sales of the TIDI Products to customers outside the Territory without the prior knowledge and written consent of TIDI except as expressly authorized herein and as may be required by law. If the territory includes the European marketplace then the Distributor and/or Importer must comply with the regulations set forth by The European Medical Device Regulation (MDR) in Exhibit D ("Importer and Distributor Requirements under MDR").
- 1.2. Reservation of Rights by TIDI. TIDI reserves the right from time to time, in its sole and absolute discretion and without liability of any type, kind or nature to Distributor (any claim for which is expressly disclaimed by Distributor) to: (i) change, add to, or delete from the list of the TIDI Products; (ii) change or modify the design or specifications of the TIDI Products; and (iii) change or terminate the level or type of service, support, or warranties that TIDI generally makes available with respect to the TIDI Products by reasonable advance written notice to Distributor prior to the effective date of the change.

2. OBLIGATIONS OF DISTRIBUTOR

- 2.1. Promotion of TIDI Products. Distributor shall use commercially reasonable efforts to promote the distribution of TIDI Products in the Territory in accordance with the terms and conditions hereof and in accordance with applicable laws and regulations.
- 2.2. Adaptation for Differing Market; Translation of Materials.
- 2.2.1 TIDI shall translate, at its sole expense, all TIDI labeling which accompanies the TIDI Products, including without limitation all manuals, packaging and labeling materials used in connection with the TIDI Products (the "TIDI Product Materials") into the following language(s) of the Territory: English, French, Spanish, Dutch, German, Italian, and Portuguese. Any additional language translations are the responsibility of Distributor. .
- 2.2.2 Distributor shall be responsible for understanding all country language requirements and for translating, at its sole expense, all TIDI materials related to the TIDI Products, including without limitation all advertising materials, promotional materials, used in connection with the TIDI Products into the language(s) of the Territory into which it intends to or does distribute the TIDI Products (the "TIDI Product Materials").
- 2.2.3 Any translations required by Distributor as required by applicable law or regulation within the Territory. Such translations shall be a literal translation of the English language without changing meaning, inclusive of all English text present, and no additional text shall be added. It is Distributor's sole obligation to ensure compliance with all applicable laws or regulations, and Distributor shall be solely responsible for implementing such compliance measures relative to the foregoing requirement. Distributor shall consult with TIDI as to what changes may need to be made to TIDI Product Materials pursuant to this requirement. Distributor shall remain solely responsible for all compliance measures related to translations of the TIDI Materials regardless of any input or consultation provided by TIDI.
- 2.3. Distributor Personnel. Distributor shall train and maintain a sufficient number of capable technical and sales personnel having the knowledge and training necessary to inform, service and support customers properly concerning the key features and capabilities of the TIDI Products and, if necessary, competitive products, and to otherwise carry out the obligations and responsibilities of Distributor as set forth herein. Distributor shall be solely responsible for the breach of any provision of this Agreement by any Distributor personnel.
- 2.4. Service and Support. Distributor shall provide prompt and professional service and support for all the TIDI Products located in the Territory. Distributor shall timely respond to customers' general questions concerning use of the TIDI Products and assist customers in the diagnosis and correction of problems encountered in using the TIDI Products. All warranty claims shall be handled by TIDI.
- 2.5. TIDI Products Registration.
- 2.5.1 Except where Manufacturer is required to register TIDI medical devices by local regulation, Distributor shall be responsible for, and shall accurately and promptly undertake all necessary actions for the registration of the TIDI Products for compliance with all required government registrations and marketing authorizations necessary to sell the TIDI Products within the Territory. TIDI shall cooperate in all material respects to promptly provide Distributor with all requisite TIDI Product information necessary to obtain such product registrations. TIDI will provide evidence/documentation that the subject device(s) complies with the local/regional regulatory requirements in order to support such product registration efforts as well as evidence

that the manufacturer has applied appropriate Conformity Assessment procedures (as defined by the regional governmental authority), as applicable.

2.5.2 Distributor acknowledges the obligation to act on behalf of TIDI Products relative to certain product registration and post market requirements, as defined by market regulation or requirement. The requirements include, but are not limited to:

- 2.5.1 Maintaining a quality management system suitable and applicable to requirements as a distributor;
- 2.5.2 Representing TIDI in interactions with The Medicines and Healthcare products Regulatory Agency or an agency within the The Medicines and Healthcare products Regulatory Agency (hereinafter "Competent Authority");
- 2.5.3 Collaborating with TIDI for the purposes of serving as the first point of contact for handling customer complaints and forwarding to TIDI, and adverse event reporting to the Competent Authority in a timely manner as set forth by the local requirements;
- 2.5.4 Collaborating with TIDI for the purposes of facilitating field actions/recalls;
- 2.5.5 Notification of substantial changes to form, fit or function that may require notification or other registration activities to the local Competent Authority; and
- 2.5.6 Maintenance of distribution, service and/or complaint records according to established records retention procedures.

2.6. No Competing Products. Distributor shall not represent or distribute during the Term of this Agreement and for a period of twelve (12) months thereafter any products which, in TIDI's reasonable opinion, compete (either directly or indirectly) with any of the TIDI Products. ~~Distributor acknowledges and agrees that sufficient consideration has been conveyed to Distributor in exchange for such agreement to exclusively distribute TIDI Products and not products competitive therewith.~~

2.7. Distributor Covenants. Distributor shall:

2.7.1 Conduct business in a manner that reflects favorably at all times on the TIDI Products and the good name, good will and reputation of TIDI including only utilizing the TIDI brand name and logos in connection with legitimate sales activities;

2.7.2 Avoid deceptive, misleading or unethical practices that are or might reasonably be expected to be detrimental to TIDI, the TIDI Products or the general public;

2.7.3 Make no false or misleading representations with regard to TIDI or the TIDI Products;

2.7.4 Not publish or employ, or cooperate in the publication or employment of, any misleading or deceptive advertising material with regard to TIDI or the TIDI Products. Ensure that advertising materials are consistent with the intended purpose of the medical device and regulatory license/registration;

2.7.5 Make no warranties or guarantees to customers or to the trade with respect to the specifications, features or capabilities of the TIDI Products that are inconsistent those provided by TIDI;

2.7.6 Except for sales made in the manner forth in Section 9.6 below, shall not sell or divert any TIDI Products outside its Territory or in any market commonly referred to as the "grey market."

2.7.7 Not disassemble, decompile, or reverse engineer any TIDI Products; copy or otherwise reproduce any TIDI Products, in whole or in part, either by itself or by another vendor; nor modify any TIDI Products in any manner without the prior written consent of TIDI.

2.7.8 Comply with TIDI's ethical standards and complaint reporting policies and procedures in effect at all times. This includes reporting to TIDI any product performance or quality issues, particularly those that result in potential or actual injury/death to the patient or caregiver within prescribed timelines. Distributor is also responsible for participating in product field actions/recalls per TIDI procedures and/or local regulatory requirements..

2.7.9 Distributor represents and warrants that: (i) it is not on an SDN List (defined below), nor is it directly or indirectly owned or controlled by an SDN (defined below); and (ii) the purchase and sale of the TIDI Products, and the consummation of any other transaction contemplated by this Agreement, will not violate any country sanctions program administered and enforced by the Office of Foreign Assets Control (OFAC) of the U.S. Department of the Treasury. For the purposes hereof, an SDN List is defined as one of the lists published by OFAC of individuals and companies owned or controlled by, or acting for or on behalf of, OFAC targeted countries, as well as individuals, groups, and entities, such as terrorists and narcotics traffickers, designated under OFAC programs that are not country-specific, and an SDN is one of the individuals or companies listed on an SDN List.

2.7.10 Neither the Distributor, any subsidiary of Distributor, nor any of their respective directors, officers, agents, stockholders or employees acting on behalf of the Distributor, has taken any action that will is or would be in breach of any applicable laws for the prevention of fraud, bribery, corruption, racketeering, money laundering or terrorism, including but not limited to the U.S. Foreign Corrupt Practices Act, as amended, the Canadian Corruption of Foreign Officials Act, as amended. The Distributor has not, and covenants that it will not, in connection with the conduct of its business activities, promise, authorize, ratify or offer to make, or take any act in furtherance of any payment, contribution, gift, reimbursement or other transfer of anything of value, or any solicitation, directly or indirectly: (i) to any individual including government officials; or (ii) to an intermediary for payment to any individual including government officials; or (iii) to any political party for the purpose or effect of public or commercial bribery, acceptance of or acquiescence in extortion, kickbacks or other unlawful, illegal or improper means. The Distributor has not, nor to Distributor's knowledge, have any of the Distributor's directors, officers, agents, stockholders or employees acting on behalf of the Distributor established or maintained any unrecorded fund or asset for any purpose, or has made any false or artificial entries on any of its books or records for any reason.

2.8. Reporting Obligations. Distributor will provide periodic reports to TIDI, at times and in a format and in detail as reasonably directed by TIDI (not less than annually), describing Distributor's

marketing and sales efforts, pricing philosophies, prospects, and the outlook for the distribution of the TIDI Products into the marketplace.

Distributor will confer with TIDI from time to time at the request of TIDI on matters relating to market conditions, sales forecasting and product planning relating to the TIDI Products.

2.9. Costs and Expenses. Except as expressly provided herein or agreed to in writing by TIDI and Distributor, Distributor shall pay all costs and expenses incurred in the performance of Distributor's obligations under this Agreement.

2.10 European Data Protection Laws. Distributor agree to comply with all rules and technical requirements of all European Data Protection Laws, as defined and set forth in Exhibit E hereto.

3. ORDER PROCEDURE

3.1. TIDI Acceptance. All orders for the TIDI Products by Distributor shall be subject to acceptance in writing by TIDI ("Order Acknowledgement") at its principal place of business and shall not be binding until the earlier of such Order Acknowledgement or shipment and, in the case of acceptance by shipment, only as to the portion of the order actually shipped.

3.2. Controlling Terms. The terms and conditions of this Agreement and of TIDI's international general terms and conditions attached hereto as Exhibit C ("Terms and Conditions"), shall apply to each order accepted or shipped by TIDI hereunder. The terms and provisions of Distributor's form of purchase order or other business forms shall not apply to any order notwithstanding TIDI's acknowledgment or acceptance of such order. The terms and conditions of this Agreement and the Terms and Conditions shall control under all circumstances. To the extent of any inconsistency between this Agreement and TIDI's Terms and Conditions, the terms and provisions of this Agreement shall control.

4. PRICES

During the term of this Agreement, TIDI shall inform Distributor as to current prices with respect to the TIDI Products to be charged to Distributor. TIDI may change its prices to Distributor from time to time by giving no less than thirty (30) days prior written notice to Distributor. Distributor acknowledges that the prices charged to Distributor may not reflect the lowest prices TIDI charges for the TIDI Products.

5. SHIPMENT, RISK OF LOSS AND DELIVERY

5.1. Shipment. Shipping terms shall be as set forth in TIDI's Terms and Conditions.

5.2. Title and Risk of Loss. Title and risk of loss shall pass to Distributor in the manner set forth in TIDI's Terms and Conditions.

6. DISTRIBUTOR'S DETERMINATION OF PRICING

Distributor shall determine the actual resale prices at which the TIDI Products shall be sold to Distributor's customers within the Territory in Distributor's sole and absolute discretion.

7. TRADEMARKS, TRADE NAMES, LOGOS, DESIGNATIONS, COPYRIGHTS AND DOMAIN NAMES

- 7.1. Use During Agreement. During the Contract Term of this Agreement and subject to the terms and conditions set forth herein, each party grants to the other party a nonexclusive, nontransferable, limited license to use, in the Territory, the other party's trademarks, trade names, logos, designations, and copyrights. Except for the limited purpose of Distributor selling the balance of such inventory of TIDI Products not repurchased by TIDI under Section 9.4 herein, such limited licenses granted herein shall immediately terminate upon termination or expiration of this Agreement without further action of either party.
- 7.2. Copyright and Trademark Notices. Distributor will include on each TIDI Product that it distributes and on all containers and storage media therefore, all trademark, copyright and other notices of proprietary rights included by TIDI on such TIDI Product. Distributor shall not alter, erase, deface or overprint any such notice on anything provided by TIDI. Distributor also shall include the appropriate trademark notices when referring to any TIDI Product in advertising and promotional materials.
- 7.3. Distributor Does Not Acquire Proprietary Rights. Distributor has paid no material consideration for the use of TIDI's patents, trademarks, trade names, logos, designations, copyrights, know-how, and trade secrets relating to the design, manufacture, marketing, operation and service of the TIDI Products, and nothing contained in this Agreement will give Distributor any right, title or interest in any of such items (collectively "Intellectual Property"). Distributor acknowledges that TIDI owns and retains all Intellectual Property and other proprietary rights in or associated with TIDI Products, and agrees that it shall not at any time during or after this Agreement assert or claim any interest in or do anything that might reasonably be expected to adversely affect the validity of any Intellectual Property belonging to TIDI (including, without limitation any act or assistance to any act, which may infringe or lead to the infringement of any of TIDI's proprietary rights). TIDI grants Distributor no right to (and Distributor shall not) copy, duplicate, reverse engineer or otherwise reproduce any of the TIDI Products.
- 7.4. No Continuing Rights. Except for purposes of selling the balance of such inventory of TIDI Products not repurchased by TIDI under Section 9.4 herein, upon the expiration or termination of this Agreement, Distributor shall immediately cease all display, advertising and use of all TIDI Intellectual Property and will not thereafter use, advertise or display any trademark, trade name, logo, designation, or copyright which is, or any part of which is, similar to or confusing with any trademark, trade name, logo, designation, copyright or domain name associated with any TIDI Product, and further Distributor shall promptly modify (if applicable) the formal legal name of the entity such that Distributor's name shall not utilize the words "TIDI," "TIDI Products," or any reasonable derivation thereof.
8. Assignment: Assignment terms shall be as set forth in TIDI's Terms and Conditions.

9. DURATION AND TERMINATION OF AGREEMENT

- 9.1. Term. This Agreement will begin on the Effective Date and will continue for a period of twelve (12) months thereafter unless previously terminated in accordance with the provisions hereof. Unless or until earlier terminated as otherwise provided herein, this Agreement shall automatically renew for six (6) month periods (the initial twelve (12) month period and each subsequent six (6) month period being a "Contract Term") thereafter provided, however, that neither party sends to the other party written notice of its intent not to renew this Agreement not less than thirty (30) days prior to the expiration of the then applicable Contract Term. The period

from the Effective Date to the date of expiration or termination of this Agreement shall be referred to as the "Term".

9.2. Termination for Breach. Without affecting any other rights that it may be entitled to, either party may give notice in writing to the other immediately terminating this Agreement immediately if:

9.2.1 the other party fails to pay any amount due under this Agreement on the due date for payment and remains in default not less than (ten) 10 days after being notified in writing to make such payment; or

9.2.2 the other party commits a material breach of any term of this Agreement and fails or is otherwise unable to remedy that breach within a period of five (5) business days of being notified in writing to do so, provided, however, that no right to cure shall exist for a breach of Section 2.1 herein by Distributor; or

9.2.3 the other party suspends, or threatens to suspend, payment of its debts or is deemed to be insolvent, unable to pay its debts as they fall due for payment, or admits inability to pay its debts; or

9.2.4 the other party commences negotiations with all or any class of its creditors with a view to rescheduling any of its debts, or enters into any composition or arrangement with its creditors generally; or

9.2.5 an order is made, a resolution is passed, or a notice is issued convening a meeting for the purpose of passing a resolution, or any analogous proceedings are taken, for the winding up, administration or dissolution of that other party; or

9.2.6 a liquidator, trustee in bankruptcy, receiver, administrative receiver, administrator or similar officer is appointed over, or in respect of, the other party or any of its business or assets; or

9.2.7 a creditor or encumbrancer of the other party attaches or takes possession of, or a distress, execution, sequestration or other such process is levied or enforced on or sued against, the whole or any part of its assets and such attachment or process is not discharged within fourteen (14) days; or

9.2.8 any event occurs, or proceeding is taken, with respect to the other party in any jurisdiction to which it is subject that has an effect equivalent or similar to any of the events mentioned in Section 9.2.3 to Section 9.2.7; or

9.2.9 the other party suspends or ceases, or threatens to suspend or cease, to carry on all or a substantial part of its business; or

9.2.10 except for sales made in the manner set forth in Section 9.6 below, Distributor sells or otherwise diverts any TIDI Products outside of its authorized Territory.

9.3. Termination At Will. Notwithstanding any other provisions contained in this Agreement, either party may terminate this Agreement at will, at any time during the term of this Agreement thereof, with or without cause, by written notice given to the other party not less than thirty (30) days prior to the effective date of termination.

- 9.4. Effect of Termination. TIDI may following termination or expiration repurchase from Distributor any saleable, non-obsolete stocks of the TIDI Products at the same price the Distributor paid for them, less a 25% restocking fee. Under all circumstances upon the termination or expiration of this Agreement, Distributor shall cooperate with TIDI and provide TIDI with all requisite assistance in the transfer of any product registrations and the transfer of any current customer contracts and relationships. Unless such termination results from a breach of the Agreement as contemplated in Section 9.2, TIDI shall reasonably compensate Distributor for its time and resources in assisting with the transfer of such product registrations. The obligations of Distributor contained in Sections 2.7.7 and 7.3 herein regarding reverse engineering of the TIDI Products shall survive the termination or expiration of this Agreement.
- 9.5. Sale of TIDI Products Outside of Authorized Territory. Should TIDI determine in its reasonable discretion that Distributor has sold or otherwise diverted any of the TIDI Products outside of its authorized Territory as defined herein in violation of this Agreement, TIDI may immediately terminate this Agreement upon written notice to Distributor with no right to cure. TIDI may also audit all of Distributor's books and records relating to Distributor's sales or other activities relating to the TIDI Products upon request, and if it is determined that Distributor has sold or diverted any TIDI Products outside the Distributor's authorized Territory, Distributor shall promptly reimburse TIDI for all costs and expenses incurred by TIDI related to such audit. This section shall not apply to sales made by Distributor in the manner set forth in Section 9.6 below.
- 9.6. Electronic Sales. Notwithstanding the provisions of Section 9.5 above, Distributor shall be entitled to resell the TIDI Products via the internet, email, or any other electronic means, provided that any website, email, or other electronic means used for this purpose is not specifically targeted at customers outside of the Territory.
10. Indemnification: Indemnification terms shall be as set forth in TIDI's Terms and Conditions.

11. LIMITED WARRANTY

Each party represents, warrants and covenants that:

11.1.1 It is duly organized, validly existing, and in good standing under the laws of its country of origin.

11.1.2 The execution and delivery of this Agreement by such party and the transactions contemplated hereunder have been duly and validly authorized by such party.

11.1.3 Such party has the power and authority to execute and deliver this Agreement and to perform its obligations hereunder.

11.1.4 The execution, delivery and performance of this Agreement do not and will not violate, result in a breach of, or constitute a default under, any agreement or business arrangement to which such party is a party or by which such party is bound.

11.1.5 Such party, nor any of its directors, officers or employees has had, or during the Term of this Agreement shall have, a complaint filed against it, by any enforcement agency, which complaint alleges either felony criminal acts of a violent nature or any crime relating to the practice of medicine.

11.1.6 Each party shall cause all of its Personnel to comply with all applicable laws and regulations.

11.1.7 During the Term, such party shall not, and shall cause none of its officers, directors or employees, to knowingly engage, directly or indirectly, in any activity which materially conflicts with its faithful performance of its duties, covenants, commitments and obligations undertaken and to be performed pursuant to this Agreement.

11.1.8 Each party shall notify the other party immediately of any action, proceeding or investigation relating to the TIDI Products or if any of the foregoing representations, warranties or covenants shall no longer be true, correct and complete. In addition, each party shall immediately notify the other party, and shall cause its directors, officers and employees to immediately notify the other party of any violations or suspected violations of law, regulation, code, or company policies or procedures relating to legal or regulatory compliance matters.

12. MISCELLANEOUS

12.1 Notices. All notices and demands hereunder will be in writing and will be served by personal service, mail, internationally recognized common courier delivery methods, or by confirmed facsimile or email transmission at the address of the receiving party set forth in this Section Below (or at such other different address as may be designated by such party by written notice to the other party):

If to Distributor: VIAMED LTD
15 Station Road, Cross Hills
Keighley BD20 7DT, United Kingdom
Attn: _____

If to TIDI: TIDI Products, LLC
570 Enterprise Drive
Neenah, WI 54956
Attn: Chief Commercial Officer

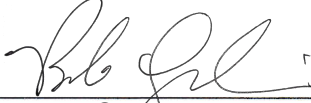
12.2 Execution of Agreement. This Agreement will become effective only after it has been signed by Distributor and has been accepted by TIDI at its principal place of business, and shall be effective on the Effective Date hereof.

12.3 Equitable Relief. Distributor acknowledges that any breach of its obligations under this Agreement with respect to the proprietary rights or confidential information of TIDI will cause TIDI irreparable injury for which there are inadequate remedies at law, and therefore TIDI will be entitled to equitable relief in addition to all other remedies provided by this Agreement or available at law.

12.4. Counterparts. This Agreement may be executed in counterparts, each of which shall be deemed an original, but all of which together shall constitute one and the same instrument.

IN WITNESS WHEREOF, the parties hereto have executed this Agreement effective on the date specified below.

TIDI Products, LLC

By: 
Name: Bob Ozélie
Title: Vice President of Finance
Date: October 19th, 2021

Company: VIAMED LTD

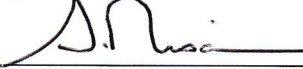
By: 
Name: STEVE NIXON
Title: DIRECTOR
Date: 10th OCTOBER 2021

EXHIBIT A
TIDI PRODUCTS

SKU#	Part Name
8168P	SECURESLEEVE PEDIATRIC
4648	POSEY REMOVABLE "ID"
4649	REMOVABLE PREMIE ID BAND
8141	POSEY IV SHIELD
8167	ARMBOARD
6554	POSEY OXIMETER PROBE WRAP
8197S	POSEY FOAM TRACH

EXHIBIT B
TERRITORY
UK

EXHIBIT C

TIDI Products, LLC

*International Distribution
General Terms & Conditions of Sale*

TIDI Products, LLC
International
General Terms & Conditions of Sale

1. **Scope and Acknowledgment.** These terms and conditions of sale (the "Terms") shall apply to all sales of goods and services ("Goods") by TIDI Products, LLC and its Affiliates ("Seller") to Buyer, and its Affiliates ("Buyer"). For purposes of these Terms, "Affiliates" shall include any entity controlled by or that control Seller or Buyer respectively, or are under common ownership of Seller or Buyer respectively.

2. **Assent to Terms.** The sale of Goods by Seller is expressly conditioned upon the assent by Buyer to these Terms and the rights of the parties shall be governed exclusively by these Terms and any corresponding pricing, manufacturing, supply, or distribution agreement between the parties (each an "Agreement"). Any attempt by Buyer to vary these Terms or any term, condition, or provision in any related Agreement in any acceptance, acknowledgment, confirmation, purchase order, or otherwise containing additional, different, or inconsistent terms and conditions (collectively "Different Terms") is hereby expressly objected to and rejected by Seller. Seller's dealings with Buyer or silence in response to Different Terms proposed by Buyer shall not be deemed acceptance of the Different Terms. No person may modify these Terms without written consent of Seller. No course of dealing or trade usage modifies these Terms. Seller reserves the right to refuse - in writing - any order from Buyer at its sole discretion. To the extent of any inconsistency between these Terms and any term, condition, or provision of any applicable Agreement between the parties, the terms, conditions, or provisions of the Agreement shall control.

3. **Shipment and Acceptance.** Shipment of an order on any specified date is subject to the availability of the Goods, and it is understood that any date specified by Seller or Buyer is an estimated and projected shipment date. SELLER SHALL NOT BE LIABLE FOR ANY LOSS, DAMAGE, OR PENALTY FOR DELAY IN SHIPMENT OR FOR FAILURE TO GIVE NOTICE OF ANY DELAY. Failure by Seller to deliver Goods by any specified shipment date shall not provide a basis for cancellation of any order. Seller may deliver Goods in advance of any shipment schedule. Upon receipt of shipment, it is Buyer's or Buyer's agent's responsibility to fully inspect the Goods for damage or other problems. Buyer shall, within forty-eight (48) hours after delivery of Goods, inspect the Goods and immediately report in writing to Seller any shortages, damages, or defects reasonably observable by proper inspection. Notwithstanding the foregoing, Buyer must (i) report any visible damage to the Goods to the carrier at time of delivery, and (ii) note the damage when signing for the Goods. If Buyer fails to inspect or report any shortages, damages, or defects as required under this section, Buyer shall be deemed to have unqualifiedly accepted the Goods. If Buyer rightfully rejects any Goods under this section, Buyer's sole remedy shall be to return the Goods pursuant to these Terms and Seller shall replace the Goods with conforming Goods, or reimburse Buyer for the net invoice price of the Goods, in Seller's sole discretion.

4. **Delivery Cost and Risk of Loss.** Except as otherwise set forth in any corresponding Agreement or accepted purchase order, delivery of Goods shall be Ex-Works Seller's applicable manufacturing facility (Incoterms, 2010). Seller is not responsible for loading, sorting, or segregating at or beyond Seller's delivery point. Seller reserves the right to make delivery in installments; all such installments are to be separately invoiced and paid for when due per invoice, without regard to subsequent deliveries. Delay in delivery of any installment shall not relieve Buyer of its obligations to accept remaining deliveries. Risk of loss and damage to Goods shall pass to Buyer upon delivery of the Goods to Seller's delivery point. It is Buyer's responsibility to be available at the time of delivery, and the shipping carrier shall determine, in its discretion, whether it will leave the Goods at Buyer's address without a signature. Goods shall be packaged and labeled in accordance with the standard labeling practices of Seller as required by applicable law. Identification of Goods shall be with Seller's part number. Except as set forth in a related Agreement, special packaging or labeling shall be an additional charge to Buyer.

5. **Pricing and Payment.** All prices shall be specified by Seller and are subject to change as set forth in Section 7 herein. Seller reserves the right to invoice at prices in effect at time of shipment if Buyer requests a shipment date more than thirty (30) days after an order is made by Buyer. Payment terms for orders are cash in advance. All past due accounts are subject to a 1.5% per month late fee. All payments must be made by check, money order, ACH or other approved electronic funds transfer (immediately available funds). Payment shall not be subject to any right of set-off. The minimum order is \$2,000.00. Except as provided otherwise by Seller, all payments must be made in U.S. currency (Dollars).

6. **Taxes and Other Charges.** Buyer shall pay all taxes, fees and duties (including without limitation, sales tax, manufacturer's tax, occupation tax, use tax, excise tax, turnover or value-added taxes, medical device tax, duty, custom, inspection or testing fee, or any other tax, fee, interest, or charge of any nature whatsoever imposed by any governmental authority, on or measured by the transaction between Seller and Buyer) or similar charges associated with the purchase of the Goods. In the event Seller is charged for such taxes or other charges, Buyer shall promptly reimburse Seller therefore.

7. **Price Adjustments.** Seller may change its prices to Buyer anytime upon not less than sixty (60) days' advance written notice.

8. **Change or Cancellation.** Signed and accepted orders are not subject to change or cancellation, except with Seller's written consent, which shall not be unreasonably withheld. Buyer shall be responsible for any costs, charges, or fees associated with an order at the time of Seller's receipt of any purported notice of change or cancellation, up to the full amount of the order. Seller reserves the right to modify, change, or replace Goods from time to time, for any reason, with reasonable notice. Seller may furnish suitable substitutes for materials unobtainable because of priorities or regulations established by governmental authority or non-availability of materials from suppliers upon reasonable notice to Buyer.

9. **Warranty/Disclaimers.** Seller warrants to Buyer that: (i) non-disposable/non-expendable/non-consumable Goods manufactured by it and sold to Buyer will be free from defects in materials and workmanship for a period of one (1) year after shipment to Buyer; (ii) disposable/expendable/consumable Goods will be free from defects in materials and workmanship for a period that terminates upon the earlier of (x) sixty (60) days after shipment to Buyer or (y) upon initial use. If, within such applicable period, any such Good shall be proved to Seller's satisfaction to be defective, such Good shall be (i) replaced at Seller's expense or (ii) the amount paid for such defective Good(s) shall be refunded, in Seller's sole and absolute discretion. Such replacement or refund shall be Seller's sole obligation and Buyer's exclusive remedy hereunder and shall be conditioned upon Seller's receiving written notice of any alleged defect within ten (10) days after its discovery and, at Seller's option, return of such Goods to Seller's facility from which the Goods originally came. **THIS WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER REPRESENTATIONS AND WARRANTIES, EXPRESS OR IMPLIED, AND SELLER EXPRESSLY DISCLAIMS AND EXCLUDES ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR ANY INFRINGEMENT OF THIRD PARTY RIGHTS, OR ANY OTHER WARRANTY ARISING FROM A COURSE OF DEALING, USAGE, OR TRADE PRACTICE.** Buyer is solely responsible for determining the appropriate use of the Goods. Seller makes no warranties or representations related to any third party goods or services. Any modification of the Goods or use inconsistent with any instructions related to the Goods by any person or entity other than Seller shall void all Seller's obligations with respect to the limited warranties and remedies provided herein. The limited warranties provided herein are conditioned upon the proper storage and use of the Goods.

10. **Limitation of Liability - Goods.** Buyer acknowledges that the price of the Goods is predicated on the enforceability of the following limitation of liability, that the price would be substantially higher if Seller could not limit its liability as herein provided, and that Buyer accepts this limitation of liability in exchange for the lower price. **ACCORDINGLY, SELLER SHALL NOT BE LIABLE, WHETHER BASED IN CONTRACT, WARRANTY, INDEMNITY, TORT (INCLUDING NEGLIGENCE), STRICT LIABILITY OR ALTERNATIVE TORT REMEDIES, OR ANY OTHER THEORY OF LAW OR EQUITY, FOR ANY INDIRECT, SPECIAL, INCIDENTAL, PUNITIVE, EXEMPLARY OR CONSEQUENTIAL DAMAGES WHATSOEVER, INCLUDING BUT NOT LIMITED TO DAMAGE TO EQUIPMENT, LOSS OF PROFITS OR REVENUE, LOSS OF USE OF PROPERTY, PLANT, EQUIPMENT, SYSTEM, OR DOWNTIME COSTS. SELLER'S TOTAL AGGREGATE LIABILITY HEREUNDER SHALL NOT EXCEED THE PURCHASE PRICE PAID BY BUYER FOR THE SPECIFIC GOODS FROM WHICH ANY CLAIM OR DAMAGES MAY ARISE.** Buyer acknowledges and agrees that any claim or cause of action that Buyer may have arising out of or relating to the Goods must be filed on or before one (1) year after such claim or cause of action arises, or forever be barred. Buyer acknowledges that Buyer's sole and exclusive remedy arising out of or in connection with these Terms or any purchase order or related Agreement between the parties shall be limited solely to the replacement of any defective or non-conforming Good(s), or a refund of the amount of the purchase price, at Seller's option.

11. **Limitation of Damages - Termination of Actual or Perceived Distribution Relationship.** IF BUYER IS A DISTRIBUTOR OR AGENT OF SELLER, SELLER SHALL NOT BE LIABLE FOR DAMAGES OF ANY KIND, INCLUDING WITHOUT LIMITATION INCIDENTAL OR CONSEQUENTIAL DAMAGES, ON ACCOUNT OF THE TERMINATION OR EXPIRATION OF ANY ACTUAL OR PERCEIVED DISTRIBUTION AGREEMENT OR ARRANGEMENT BETWEEN THE PARTIES HERETO. BUYER WAIVES ANY RIGHT IT MAY HAVE TO RECEIVE ANY COMPENSATION OR REPARATIONS ON TERMINATION OR EXPIRATION OF THESE TERMS UNDER THE LAW OF THE APPLICABLE TERRITORY OR OTHERWISE, OTHER THAN AS EXPRESSLY PROVIDED IN THESE TERMS. Except as set forth in any Agreement between the parties, this is not an exclusive distribution agreement or arrangement. Buyer may only sell the Goods into territories preapproved by Seller in writing. Upon request, Buyer shall provide documentation establishing the location and name of the customers purchasing Goods from Buyer. Seller shall be not liable to Buyer on account of termination or expiration of these Terms for reimbursement or damages for the loss of goodwill, prospective profits or anticipated income, or on account of any expenditures, investments, leases or commitments made by either Seller or Buyer or for any other reason whatsoever based upon or growing out of any termination or expiration hereof. Buyer acknowledges that (i) Buyer has no expectation and has received no assurances that any investment by Buyer in the promotion of the Goods will be recovered or recouped or that Buyer will obtain any anticipated amount of profits by virtue of these Terms, and (ii) Buyer will not have or acquire by virtue of these Terms or otherwise any vested, proprietary or other right in the promotion of the Goods or in "goodwill" created by its efforts hereunder. THE PARTIES ACKNOWLEDGE THAT THIS SECTION HAS BEEN INCLUDED AS A MATERIAL INDUCEMENT FOR SELLER TO ENTER INTO THESE TERMS AND THAT SELLER WOULD NOT HAVE ENTERED INTO THESE TERMS BUT FOR THE LIMITATIONS AS SET FORTH HEREIN.

12. **Compliance with Laws.** Buyer shall obtain all licenses, permits, and approvals required by any government or applicable authority, and shall comply with all applicable laws, rules, regulations, policies, and procedures, and any requirements applicable to the importation, exportation, use, sale, loan, purchase, destruction, and distribution of the Goods. Buyer agrees to comply with all applicable export laws and restrictions and regulations of the United States Department of Commerce or other United States agency or authority and with Seller's

U.S. Export Controls Compliance Policy incorporated herein by reference.

13. **Indemnification.** BUYER SHALL DEFEND, INDEMNIFY, AND HOLD HARMLESS SELLER, ITS OFFICERS, EMPLOYEES, AGENTS, SUCCESSORS AND ASSIGNS FROM AND AGAINST ANY AND ALL LIABILITIES, LOSSES, DAMAGES, COSTS, FINES, AND EXPENSES (INCLUDING ATTORNEYS' FEES AND DISBURSEMENTS) ARISING FROM, BASED UPON, RELATED TO, OR IN ANY WAY CONNECTED WITH (i) BUYER'S MISUSE OF SELLER'S CONFIDENTIAL INFORMATION AND INTELLECTUAL PROPERTY, OR (ii) BUYER'S FAILURE TO COMPLY WITH ITS OBLIGATIONS SET FORTH IN THESE TERMS AND ANY CORRESPONDING AGREEMENT, AND WITH ANY APPLICABLE LAW, REGULATION, TREATY OR ORDER.

14. **Returns.** Approval for the return of any Goods must be obtained from Seller prior to such return and any returned Goods must be identified by a "Return Authorization Number" provided by the Seller. Buyer should contact a Customer Relations Representative to obtain a Return Authorization Number. If the return of Goods is approved, at Seller's sole discretion, returned Goods must be securely packaged to reach Seller without damage. Goods may only be returned within sixty (60) days of delivery of the Goods and must have a shelf life of not less than six (6) months upon receipt by TIDI. All sterile Goods must be returned in original, unopened, and undamaged packages. Returned Goods will be credited at the net invoice price at the time of purchase. Goods authorized for return other than delivery or shipping error on the part of Seller or defectiveness in materials or workmanship must be returned freight pre-paid, and are subject to a 25% restocking charge. Return of Goods having a remaining shelf life of less than six (6) months is prohibited.

15. **Liens and Claims.** To the fullest extent allowable by law, Seller retains all lien rights and claims against property for supplying Goods to Buyer. Buyer shall be fully responsible for all payments and claims if lien rights are found unenforceable for any reason. Upon full payment, Seller will release all lien claims against Buyer. Buyer hereby grants to Seller a security interest in all Goods delivered to Buyer until such time as Seller is paid in full for such Goods.

16. **Force Majeure.** Seller shall not be liable for any claim, expense, loss, or damage arising from Seller's delay in performing, or failure to perform, as a result of equipment failures, power failures, strikes, labor disputes, riots, insurrections, civil disturbances, shortages of materials, fires, floods, storms, explosions, acts of god, war, governmental actions, orders of domestic or foreign courts or tribunals, non-performance by third parties, or any other occurrence or loss beyond the reasonable control of Seller.

17. **Dispute Resolution.** These Terms shall be governed by and construed in accordance with the internal laws of the State of Wisconsin, U.S.A., without application of choice of laws principles. In the event of a controversy arising under these Terms, the parties shall first consult and negotiate with each other in an attempt to reach a solution acceptable by both parties. If such a solution is not achieved within sixty (60) days from the first day either party delivers notice in writing that such consultations or negotiations must occur, then any dispute, controversy, or claim arising out of these Terms, including its interpretation, performance, or termination shall be finally resolved by binding arbitration. The arbitration, including the rendering of the award shall be by a single arbitrator. The decision of the arbitrator shall be binding upon the parties, and each party shall bear its own costs (including without limitation, attorneys' fees). The decision of the arbitrator shall be executory, and judgment thereon may be entered by any court of competent jurisdiction. If the amount in dispute is less than the equivalent of U.S. \$500,000.00, then the arbitration shall be governed by the Commercial Arbitration Rules then in effect of the American Arbitration Association and the place of arbitration shall be Chicago, IL, U.S.A. If the amount in dispute is greater than the equivalent of U.S. \$500,000.00, then the arbitration shall be governed by arbitration under the Rules of Arbitration of the International Chamber of Commerce ("ICC") then in effect and the place of arbitration shall be

Chicago, IL, U.S.A. The Arbitrator shall have no authority or jurisdiction or power to alter, amend, change, modify, add to or subtract from any provisions of these Terms or to decide any issues or controversies other than those set forth in the Notice of Arbitration. Notwithstanding the foregoing, the obligation herein to arbitrate shall not be binding upon any party with respect to requests for preliminary injunctions, temporary restraining orders, specific performance, or similar procedures in a court of competent jurisdiction to obtain interim relief when deemed necessary by such court to preserve the status quo or prevent irreparable injury pending resolution by arbitration of the actual dispute. All proceedings shall be conducted in English. Buyer waives any objection that it may have based on improper venue or forum non conveniens to conducting the arbitration in Chicago, IL, U.S.A. The United Nations Convention on Contracts for the International Sale of Goods shall not apply to these Terms or any sale of Goods between Buyer and Seller.

18. **Waiver.** Failure by Seller to insist upon strict performance of any Terms shall not be considered a continuing waiver of such Terms or any of Seller's rights hereunder.

19. **Successors, Assigns and Affiliates.** These Terms are binding upon and shall inure to the benefit of the parties, their Affiliates, and their respective heirs, executors, legal representatives, successors, and permitted assigns. Buyer may not, directly or indirectly, assign, delegate, transfer, convey, or subcontract all or any portion of its rights, duties, and obligations under these Terms without the prior written consent of Seller, which may be withheld at Seller's sole discretion, except in the case of an assignment to a subsidiary of Buyer where Buyer remains liable for such subsidiary's payment and performance.

20. **Independent Contractors.** Each of the parties to this order is an independent contractor. Neither party has or will have any power to bind the other party or to assume or create any obligation or responsibility, express or implied, on behalf of the other party. The parties do not intend to create any agency, partnership, joint venture, or like relationship through these Terms. Buyer is not earning commissions for the sale of Goods and Buyer expressly acknowledges and agrees that it is not an agent of the Seller, and it is not subject to mandatory indemnity or compensation upon provisions contained in EU Directive 86/653, the European Self-Employed Agents Directive Act.

21. **No Third Party Beneficiary.** Neither these Terms or any order of Goods is intended to create any right, claim, or remedy in favor of, or impose any obligation upon, any person or entity other than the parties hereto.

22. **Severability.** If any section of these Terms is held by a court of competent jurisdiction to be illegal, or unenforceable for any reason, such determination shall not affect the remainder of this order.

23. **Electronic Transactions.** The parties intend that these Terms can be electronically submitted and accepted, that the email addresses provided on any attached order or sales documents can be used to provide any required notice or communications, and that the electronic transactions provisions in 15 U.S.C. 96 (Electronic Signatures in Global and National Commerce) apply to these Terms and/or any related Agreement.

24. **Food and Drug Administration.** Claims and statements made by Seller about specific Goods may not have been evaluated by the United States FDA (Food and Drug Administration). Buyer should consult with a qualified healthcare professional or physician before use of any Goods.

25. **Emergency Product Allocation.** In the event of a shortage of any Goods, as determined solely by Seller, Seller shall allocate sales of Goods among purchasers in its sole discretion.

26. **Confidentiality.** Buyer acknowledges that, unless and only to the extent Seller specifically agrees to the contrary in advance in writing, these Terms, and all other information as to quantity, cost, and prices charged to Buyer by Seller for Goods, all information relating to

marketing, Goods, designs, ideas, sales volume, and data regarding Seller, sketches, specifications, prototypes, models, and samples, or any design or production techniques, and other information identified or reasonably identifiable as confidential or proprietary, shall be maintained in confidence by Buyer (hereinafter the "Confidential Information"). The confidentiality obligations of this section shall not apply to information which (i) Buyer is compelled to disclose by judicial or administrative process; provided that Buyer shall promptly give Seller advance notice of its intention to make such disclosure so that Seller may have the opportunity to prevent or restrict such disclosure if it deems such prevention or restriction in its best interest; (ii) Buyer can show to have been generally available to the public other than as a result of a breach of this section; (iii) Buyer can show was within its legitimate possession prior to the time of disclosure by Seller; or (iv) is disclosed to Buyer by a third party having legitimate possession thereof and the unrestricted right to make such disclosure. Buyer's burden of proof is by clear and convincing evidence with respect to exceptions (i) to (iv) above. This obligation of confidentiality is for five (5) years from the date of the last purchase of the Goods, except for Confidential Information that is defined under the laws of the State of Wisconsin, U.S.A. as a trade secret, which shall remain confidential for the maximum period of time allowed under the laws of the State of Wisconsin, U.S.A. Buyer acknowledges that the Confidential Information of Seller is valuable to Seller, and there is no adequate remedy at law for a breach of these Terms, and Seller will be entitled to an injunction to prevent and restrain the use of Confidential Information other than as authorized herein in addition to any other remedies available at law or equity.

27. **No Gratuities or Hidden Payments.** Seller has not paid any gratuities, fees, or payments of any kind to any officer, employee, director, agent, or representative of Buyer to induce an order, and Seller has not made, directly or indirectly, any gift to or bestowed any benefit on any officer, employee, director, agent, or representative of Buyer, or directly or indirectly entered into any business or financial arrangement with any of them to induce an order. Buyer represents, warrants and covenants that it shall not make any payments, in money or other items or services of value to (i) any government official, (b) any foreign political party, (c) any candidate for foreign political office or (d) any other person or entity, with the knowledge that such payment, offer or compromise to pay or provide items or services of value are being made to any such person for the purpose of influencing such person to make one or more business decisions favorable to Buyer. Buyer further represents warrants and covenants that no government official is a principal, owner, officer, employee or agent of any entity that Buyer has an interest in, and not government official has any material financial interest in the business of Buyer. Buyer shall review Seller's Foreign Corrupt Practices Act Policy, to comply with such policy, and to annually certify such compliance by executing a certification presented by Seller from time to time.

28. **Indemnification for Intellectual Property Infringement.** As to any Goods Seller furnishes to Buyer manufactured in accordance with drawings, designs, or specifications proposed or furnished by Buyer, or any claim of contributory infringement resulting from the use or resale by Buyer of Goods sold hereunder, Seller shall not be liable. Buyer shall indemnify Seller and hold Seller harmless from and against any and all loss, liability, damage, claim, and expense (including but not limited to Seller's reasonable attorneys' fees and other costs of defense) incurred by Seller as a result of any claim of patent, trademark, copyright, trade secret, or other intellectual property theft or infringement, or infringement of any other proprietary rights of third parties based on Goods being manufactured and sold by Seller in accordance with drawings, designs, and specifications furnished by Buyer.

29. **Intellectual Property.** Seller retains all right, title and interest in and to all design concepts, designs, drawings, specifications, samples, ideas, and materials, including any derivative works and works based on such items, and including all trade secret, trademark, copyright, patent, and all other intellectual property and proprietary rights therein, for anything it creates, develops, prepares, or sells, either alone or jointly with any employees, agents, or subcontractors of Buyer, in the course of

performing under these Terms (hereinafter the "Work Product"). Buyer agrees that it shall execute and cause its employees, agents, and subcontractors to execute all documents necessary or convenient to allow Seller to perfect Seller's interest in the Work Product. Buyer agrees not to reverse engineer any Work Product.

30. **License.** Each party grants to the other party with immediate effect a personal, non-exclusive, limited, and non-sublicensable license to perform the obligations under these Terms or any Agreement. Such limited license shall immediately terminate upon termination or expiration of these Terms or any related Agreement between the parties without further action of either party.

31. **Recall Policy Statement.** Seller maintains a recall policy per its quality system procedure. This procedure addresses the requirements of Clause 8.5 in EN/ISO 13485 and Section 8.5 in Seller's QMS Manual, and Part 806 of the FDA 21 CFR regulations. Within this procedure, the Director of Regulatory Affairs is responsible for coordination of all information in a potential recall situation as well as defining and monitoring the activities during an actual recall event.

32. **Entire Agreement.** These Terms, when accompanied by a related Agreement between the parties and/or a written quotation from the Seller, shall constitute the final expression of the agreement of the parties and is the complete and exclusive statement of its terms. Catalogues, photographs, drawings, and other illustrations shall not form a part of these Terms or any related Agreement unless expressly agreed to by Seller, in writing.

33. **Cumulative Remedies.** No remedy conferred upon Seller is intended to be exclusive of any other remedy, and each and every such remedy shall be in addition to, and not in limitation of or substitution for, every other remedy available at law or in equity or by statute or otherwise.

34. **Headings.** The headings contained in these Terms are for convenience of reference only and shall not affect the meaning or construction of any of its provisions.

35. **Incorporation by Reference.** These Terms shall be incorporated by reference into any agreement between Buyer and any of Buyer's distributors or resellers. If there is a conflict between the provisions of any such agreement and these Terms, these Terms shall control. Buyer acknowledges that Seller shall not be bound by any terms of any agreement between Seller and Seller's distributors or resellers.

36. **Ordering.** To place an order by telephone, Buyer should call Seller's Customer Relations Department at 800/521-1314, fax to 800/837-7770, or email to excellence@TIDIProducts.com. To contact Seller by mail, Buyer should write to: TIDI Products, LLC, P.O. Box 806, Neenah, WI 54957-0806. All orders for Goods by Buyer shall be subject to acceptance in writing by Seller ("Order Acknowledgement") at its principal place of business and shall not be binding until the earlier of such Order Acknowledgement or shipment and, in the case of acceptance by shipment, only as to the portion of the order actually shipped.

37. **Related Documentation.** Buyer acknowledges receipt of and shall comply with Seller's notice regarding Shipper's Export Declaration and Seller's U.S. Export Controls Compliance Policy.

EXHIBIT D

IMPORTER AND DISTRIBUTOR REQUIREMENTS UNDER MDR

1. General Obligations of Importers

- a. Importers shall place on the Union market only devices that are in conformity with this Regulation.
- b. In order to place a device on the market, importers shall verify that:
 - i. the device has been CE marked and that the EU declaration of conformity of the device has been drawn up;
 - ii. a manufacturer is identified and that an authorised representative in accordance with Article 11 has been designated by the manufacturer;
 - iii. the device is labelled in accordance with this Regulation and accompanied by the required instructions for use;
 - iv. where applicable, a UDI has been assigned by the manufacturer in accordance with Article 27.
 - v. Where an importer considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, it shall not place the device on the market until it has been brought into conformity and shall inform the manufacturer and the manufacturer's authorised representative. Where the importer considers or has reason to believe that the device presents a serious risk or is a falsified device, it shall also inform the competent authority of the Member State in which the importer is established.
- c. Importers shall indicate on the device or on its packaging or in a document accompanying the device their name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted, so that their location can be established. They shall ensure that any additional label does not obscure any information on the label provided by the manufacturer.
- d. Importers shall verify that the device is registered in the electronic system in accordance with Article 29. Importers shall add their details to the registration in accordance with Article 31.
- e. Importers shall ensure that, while a device is under their responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I and shall comply with the conditions set by the manufacturer, where available.
- f. Importers shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and provide the manufacturer, authorised representative and distributors with any information requested by them, in order to allow them to investigate complaints.
- g. Importers who consider or have reason to believe that a device which they have placed on the market is not in conformity with this Regulation shall immediately inform the manufacturer and its authorised representative. Importers shall co-operate with the manufacturer, the manufacturer's authorised representative and the competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or recall it is taken. Where the device presents a serious risk, they shall also immediately inform the competent authorities of the Member States in which they made the device available and, if applicable, the notified body that issued a certificate in accordance with Article 56 for the device in question, giving details, in particular, of the non-compliance and of any corrective action taken.
- h. Importers who have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device which they have placed on the market shall immediately forward this information to the manufacturer and its authorised representative.
- i. Importers shall, for the period referred to in Article 10(8), keep a copy of the EU declaration of conformity and, if applicable, a copy of any relevant certificate, including any amendments and supplements, issued in accordance with Article 56.
- j. Importers shall cooperate with competent authorities, at the latter's request, on any action taken to eliminate or, if that is not possible, mitigate the risks posed by devices which they have placed on the market. Importers, upon request by a competent authority of the Member State in which the importer has its registered place of business, shall provide samples of the device free of charge or, where that is impracticable, grant access to the device.

2. General Obligations of Distributors

- a. When making a device available on the market, distributors shall, in the context of their activities, act with due care in relation to the requirements applicable.
- b. Before making a device available on the market, distributors shall verify that all of the following requirements are met:
 - i. the device has been CE marked and that the EU declaration of conformity of the device has been drawn up;

- ii. the device is accompanied by the information to be supplied by the manufacturer in accordance with Article 10(11);
 - iii. for imported devices, the importer has complied with the requirements set out in Article 13(3);
 - iv. that, where applicable, a UDI has been assigned by the manufacturer.
- c. In order to meet the requirements referred to in points (i), (ii) and (iv) of the first subparagraph the distributor may apply a sampling method that is representative of the devices supplied by that distributor.
- d. Where a distributor considers or has reason to believe that a device is not in conformity with the requirements of this Regulation, it shall not make the device available on the market until it has been brought into conformity, and shall inform the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. Where the distributor considers or has reason to believe that the device 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.
- e. Distributors shall ensure that, while the device is under their responsibility, storage or transport conditions comply with the conditions set by the manufacturer.
- f. Distributors that consider or have reason to believe that a device which they have made available on the market is not in conformity with this Regulation shall immediately inform the manufacturer and, where applicable, the manufacturer's authorised representative and the importer. Distributors shall co-operate with the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer, and with competent authorities to ensure that the necessary corrective action to bring that device into conformity, to withdraw or to recall it, as appropriate, is taken. Where the distributor considers or has reason to believe that the device 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, in particular, of the non-compliance and of any corrective action taken.
- g. Distributors that have received complaints or reports from healthcare professionals, patients or users about suspected incidents related to a device they have made available, shall immediately forward this information to the manufacturer and, where applicable, the manufacturer's authorised representative, and the importer. They shall keep a register of complaints, of non-conforming devices and of recalls and withdrawals, and keep the manufacturer and, where available, the authorised representative and the importer informed of such monitoring and provide them with any information upon their request.
- h. Distributors shall, upon request by a competent authority, provide it with all the information and documentation that is at their disposal and is necessary to demonstrate the conformity of a device.
- i. Distributors shall be considered to have fulfilled the obligation referred to in the first subparagraph when the manufacturer or, where applicable, the authorised representative for the device in question provides the required information. Distributors shall cooperate with competent authorities, at their request, on any action taken to eliminate the risks posed by devices which they have made available on the market. Distributors, upon request by a competent authority, shall provide free samples of the device or, where that is impracticable, grant access to the device.

EXHIBIT E

EUROPEAN DATA PROTECTION LAWS

1. In performing the services pursuant to the Agreement, Distributor may be required to process certain personal data that is subject to Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of Personal Data and on the free movement of such data, and repealing Directive 95/46/EC ("GDPR") or the United Kingdom GDPR (collectively, "European Data Protection Laws"). Distributor represents and warrants that it will comply with European Data Protection Laws, including by: (i) maintaining written privacy policies that are compliant with European Data Protection Laws; (ii) ensuring that it has a lawful means for processing personal data; and (iii) obtaining any and all necessary consents from data subjects prior to transferring personal data to TIDI Products LLC ("TIDI"). Prior to transferring any personal data to TIDI, the parties will execute a data processing addendum in a form provided by TIDI.

2. Distributor shall implement technical and organizational measures to ensure a level of security appropriate to the risk of processing, and Distributor shall comply with all security requirements of European Data Protection Laws. Distributor shall consider the following when implementing such security measures, as appropriate: (i) pseudonymisation and encryption of personal data; (ii) the ability to ensure the ongoing confidentiality, integrity, availability and resilience of processing systems and services; (iii) the ability to restore the availability and access to personal data in a timely manner in the event of a physical or technical incident; and (iv) a process for regularly testing, assessing and evaluating the effectiveness of the technical and organizational measures for ensuring the security of the processing.

3. In the event the services require Distributor to transfer personal data out of the European Union or United Kingdom to TIDI in the United States, the parties shall execute the Standard Contractual Clauses adopted or approved by the European Commission or its successor agreement or utilize another legally approved method for transfer of personal data. The parties further agree that they shall work together to amend the Agreement and data processing addendum to substitute modified Standard Contractual Clauses within one (1) year of their approval and adoption by the European Commission.