



## Terms & Conditions of Purchase

**Acceptance - Agreement:** Roechling Medical Rochester, L.P. (referred to as RMR hereinafter) and Supplier agree that Supplier will sell to RMR Products (as defined herein) from time to time ordered pursuant to RMR's purchase order (singularly an "Order" or when used to refer to more than one Order, "Orders"), or otherwise, and that EACH ORDER THAT IS PLACED OR PURCHASE MADE SHALL BE SUBJECT TO AND GOVERNED SOLELY BY THESE TERMS AND CONDITIONS OF PURCHASE AND THE RELEVANT ORDER(S) AS SET FORTH BELOW ("AGREEMENT"). Documents designated by RMR in the body of the Order, including supplemental terms and conditions, if any, are incorporated by reference the same as if set out in full therein, and will form a part of the Order and this Agreement. Supplier's acceptance of the Order, commencement of work on the merchandise subject to the Order or shipment of such Products, whichever occurs first, shall be deemed acceptance of the Order and this Agreement. Any actual or deemed acceptance of the Order is limited to acceptance of the express terms contained in this Agreement. Any proposal for additional or different terms or any attempt by Supplier to vary in any degree any of the terms of the Order or this Agreement in Supplier's acceptance is hereby objected to and rejected, but such proposals shall not operate as a rejection of the Order or this Agreement unless such variances are in the terms of the description, quantity, price or delivery schedule of the Products, in which case they shall be deemed a material alteration thereof, and the Order and this Agreement shall be deemed accepted by Supplier without said or additional or different terms. In no event is this Agreement to be construed as exclusive or to otherwise impose any minimum or guaranteed purchases or amounts upon RMR. It is Supplier's responsibility to comply with this Agreement and to clarify with RMR any inconsistencies, ambiguities, or conflicts in any parts of this Agreement, including without limitation the Order or referenced documents. Should Supplier fail to contact RMR to resolve conflicts or inconsistencies, Supplier will be solely responsible for errors resulting from said conflicts or inconsistencies. Where documents are referenced, unless otherwise specified, the version in effect at the time of order placement shall apply.

**Purchase Orders:** Supplier shall confirm all Orders for Products (as defined herein) within three (3) business days<sup>1</sup> of receipt thereof. As used herein, "Products" shall mean custom injection molded parts, subassemblies, and inputs and materials therefor supplied in accordance with RMR's Specifications, as defined below. Supplier may not unreasonably reject any Order. In the event Supplier has a reasonable basis to reject any Order, Supplier shall so inform RMR immediately, and the parties shall work in good faith to mutually agree on any changes to the Order. RMR shall be entitled to modify the quantity of Products set forth in any Order previously submitted to Supplier by providing Supplier written notice of such modification within product lead time in advance of the delivery date for such Products; provided, however, that if RMR modifies the quantity, a corresponding, commercially reasonable change to the delivery date will be made to the extent specified as necessary by Supplier in response to the written modification sent by RMR.

**Specifications:** As used herein, "Specifications" shall mean the functional, design, product, materials and content, manufacturing, quality assurance, labeling and packaging specifications for the Products, as well as requirements, drawings, notes, instructions, engineering information or technical data furnished by RMR, or referred to in the Order. Where expressly requested or specified by RMR, "Specifications" hereunder may also include specifications furnished by Supplier concerning the Products; provided, however in the event of any conflict or ambiguity between Specifications as furnished by RMR and any similar information furnished by Supplier, the Specifications furnished by RMR shall govern. Supplier shall be fully and solely responsible for obtaining data adequate to design, manufacture, fabricate, construct and deliver any Products in compliance with all requirements of the Order. Any Products delivered to RMR under an Order will be supplied according to RMR's instructions regarding the above information and in accordance with the FDA Quality System Regulation (21 CFR Part 820) and all applicable international standards. No changes are to be made to the Specifications or the Products manufactured from those specifications without written approval from RMR. Supplier shall obtain from RMR written approval of all Specification deviations. This shall include deviations for all Products produced from tooling provided by RMR, or third parties, which are not in compliance with Specifications hereunder. As between

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Supplier and RMR, RMR shall retain title to all such tooling, Specifications and/or related documents which it provides or causes to be given to Supplier, and nothing herein shall be construed as transferring any right, title or interest of any kind or nature whatsoever thereto to Supplier. Supplier shall not use any of such tooling, documents or the information contained therein for any purpose other than in performance of the Order. Supplier shall not disclose such documents or information to any party other than RMR or a party duly authorized by RMR. Upon RMR's request, Supplier shall promptly return to RMR all such tooling, documents, and copies.

**Changes:** RMR shall have the right at any time to make changes in drawings, designs, specifications, materials, packaging, time and place of delivery and method of transportation. If any such changes cause an increase or decrease in the cost, or the time required for performance, Supplier shall notify RMR promptly following receipt of RMR's change specification at which time an equitable adjustment shall be made and the Order shall be modified in writing accordingly. Supplier hereby waives any right to claim cost increases resulting from change specifications submitted by RMR to the extent Supplier fails to notify RMR in a timely fashion, and in no event, any later than five (5) business days following receipt of the applicable RMR change specification. Supplier agrees to accept any such changes subject to this paragraph. Product design, labeling or process changes (including changes to raw materials, control plans, measurement methodology and tooling) and changes to the manufacturing location of any Products may not be made by Supplier without prior written consent from RMR.

**Production Part Approval Process ("PPAP"):** In order to affect controlled processes, Products consistency and high quality, Supplier must meet minimum performance standard as defined by the then-current Production Part Approval Process ("PPAP") plan provided by RMR. Such PPAP will specify conditions, Products and performance in furtherance of Supplier's efforts to control, test, and release Products supplied by Supplier to RMR in such a manner so as to ensure that the Products meet all of RMR's acceptance criteria, and may include sending pre-shipment samples at Supplier's cost to a specific location designated by RMR for testing, as well as procedural criteria for sampling, testing, release and rejection. Supplier hereby agrees that RMR has the right to propose modifications to the PPAP from time to time, consistent with ensuring that the Products meet all of RMR's acceptance criteria. Upon notice of such modification, Supplier shall work with RMR to implement modifications within an agreeable timeframe, to comply with the terms thereof; provided, however, Supplier may propose an equitable adjustment to the price for the Products to reflect (without markup, or additional margin) changes in costs and/or expenses directly resulting from such modification, and once such revision to the price has been agreed upon, Supplier will implement the modifications to the PPAP.

**Payment Terms:** Unless otherwise agreed by RMR and Supplier in writing, (a) payment shall be made by RMR separately for each Order, and (b) RMR shall pay all undisputed invoice amounts in U.S. dollars within established terms.

**Process Improvements:** If, at any time during the Term of this Agreement, Supplier implements process improvements that reduce Supplier's cost of production of the Products, or if there is a material decrease in the cost of raw materials used in the production of the Products, Supplier shall pass 50% of such cost savings along to RMR in the form of a decrease in the prices in place at the time the costing savings are realized. Any such price decrease shall be effective for the Products ordered in the next Order following notice of the reduced price. Notwithstanding the foregoing, in the event Supplier implements any operational excellence improvement at RMR's suggestion and under RMR's guidance, Supplier shall pass 100% of the savings attributable to such improvement along to RMR.

**Setoff:** All claims for money due or to become due from RMR shall be subject to deduction or set off by RMR by reason of any counterclaim arising out of this or any other transaction with Supplier.

**Manufacturing and Delivery Commitment:** Supplier hereby represents and warrants that it has and will maintain sufficient manufacturing capacity to meet RMR's needs of the Products as specified in the Order(s). If Supplier fails to deliver the total quantity of Products ordered by RMR in any Order by the date of delivery specified therein, then RMR may elect to (a) purchase replacement Products from an additional supplier, or (b) have the remaining portion of the order of Products shipped by air freight at Supplier's sole cost and expense. In the event that RMR purchases replacement Products or substitutes for the replacement Products from another source because Supplier is not able to deliver sufficient Products, and pays more than the then-current purchase price stipulated in the Order for



such replacement Products or for substitutes for the replacement Products, Supplier shall credit RMR the difference in price per unit of Products not delivered equal to the total amount of the shortfall. Regardless of whether RMR orders replacement or substitute Products from another source, Supplier shall remain obligated to deliver the total quantity ordered by RMR, unless RMR notifies Supplier that RMR is canceling its order with respect to the amount of the shortfall.<sup>2</sup>

**Delivery:** Supplier acknowledges and agrees that time is of the essence with respect to all delivery dates stated on Orders. Any delivery made after close of business on the date specified in the Order shall be deemed late. If any part of the Products delivered by Supplier is delivered late, or otherwise does not comply with the terms and conditions hereof or in the Order as to quality or otherwise, RMR may either (a) reject and return all or any part of the Products ordered thereunder for full credit, including freight or (b) at RMR's option, utilize all or any part of said Products, holding Supplier liable for all damages resulting from Supplier's failure to comply. Deliveries shall not be made earlier than five (5) days prior to the requested delivery date unless specified by RMR. RMR reserves the right to accept or reject partial shipments.

All shipments shall be routed per routing instructions on the face of the Order or at the request of RMR's Logistic Department. If specific routing is indicated and not complied with, all extra carriage will be charged against Supplier. In the event Supplier does not follow SHIP TO instructions on the face of the Order, which results in the Products arriving at incorrect locations, material will be reshipped at Supplier's cost and expense. In the event of an embargo, Supplier shall contact RMR's Logistic Department immediately for instructions. All Products shipped shall be at Supplier's risk until actual receipt by RMR (or its carrier of choice) at the designated delivery point in accordance with the shipping term as stated on the Order and RMR assumes no liability for loss or damage occurring prior to RMR's receipt.

Supplier shall (a) deliver a minimum of 95% of all Products ordered by RMR under the Order no earlier than the date specified by RMR for each such Order, (b) fill 100% of all Products ordered by RMR under the Order, and (c) maintain a 98% quality acceptance rating for all Products ordered under the Order.

**Shipment:** If in order to comply with RMR's required delivery date it becomes necessary for Supplier to ship a more expensive way than specified in the Order, any increased transportation costs resulting therefrom shall be paid for by Supplier unless the necessity for such rerouting or expedited handling has been caused solely by RMR and RMR agrees in advance to such rerouting or expedited handling fees. No charges of any kind, including charges for boxing or carriage, freight or special handling, will be allowed unless specifically agreed to in advance by RMR in writing. Pricing by weight, where applicable, covers net weight of material, unless otherwise agreed. Any costs incurred by RMR because of Supplier's non-compliance with the terms and conditions in an Order, shall be charged back to Supplier.

**Inspection:** RMR shall be under no duty to inspect Products purchased hereunder before its use in manufacture and/or resale, and the processing, manufacture or resale shall not constitute an acceptance of the Products or a waiver of any claim. RMR reserves the absolute right to reject and refuse acceptance of Products which is not in accordance with RMR's instructions, specifications, drawings and data or not in accordance with Supplier's warranty (express or implied) and to return same to Supplier at Supplier's expense. Payment for any Products purchased by, and delivered to, RMR hereunder shall not be deemed an acceptance thereof.

**Termination for Convenience of RMR:** RMR reserves the right to terminate the Order or any part thereof for its sole convenience. In the event of such termination, Supplier shall immediately stop all work thereunder and shall immediately cause any of its suppliers or subcontractors to cease such work. Supplier shall be paid its actual direct, non-cancellable costs already incurred prior to the notice of termination; provided that Supplier shall not be paid for any work done after receipt of the notice of termination, nor for any costs incurred by Supplier's suppliers or subcontractors which Supplier could reasonably have avoided or mitigated or with respect to materials that can be returned, redirected or resold to other customers.



**Termination for Cause:** RMR may also terminate the Order or any part thereof for cause in the event of any default by the Supplier, or if the Supplier fails to comply with any of the terms and conditions of the Order or this Agreement. For purposes of the foregoing sentence "cause" includes late delivery or performance, a delivery of defective or nonconforming goods or workmanship, failure to provide RMR, upon request, with reasonable assurances of future performance, a breach of any of Supplier's warranties, any other material default or failure of compliance by Supplier with the terms and conditions hereof, the commencement or continuance of any bankruptcy or insolvency proceeding by or against Supplier, or any legal process or order directing or requiring RMR to undertake or refrain from undertaking any business or certain types of business with the result that the goods and/or services ordered hereunder shall be unnecessary to RMR.

**Proprietary information–Confidentiality:** Products furnished to the Specifications shall not be furnished or quoted to any other person or concern or used by Supplier for any purpose other than fulfilling Orders for RMR. Such patterns, specifications and drawings along with any other non-public information or materials provided by RMR to Supplier shall be confidential, shall remain the property of RMR or its customers and shall be returned to RMR immediately upon request. Unless otherwise agreed in writing, no commercial or technical information disclosed in any manner or at any time to RMR by Supplier shall be deemed secret or confidential and Supplier shall have no rights against RMR with respect thereto except such rights as any exist under any applicable patent law. The obligations of Supplier hereunder pursuant to this section shall survive for a period of three (3) years, with the exception of designated trade secrets in which case the obligations of Supplier shall survive until such time as such trade secret is no longer a trade secret under applicable law through no fault of Supplier's.

In the event that the recipient of confidential information is requested or becomes legally compelled to disclose any of the confidential information (whether by oral questions, interrogatories, requests for information or documents, subpoena, civil investigative demand or similar process or otherwise), such recipient party will provide the disclosing party with prompt notice, to the extent practicable, so that the disclosing party may seek a protective order or other appropriate remedy and/or waive compliance with the provisions of this section related to confidentiality. In the event that such protective order or other remedy is not obtained, the disclosing party agrees that such disclosure may be made without liability hereunder; provided that the recipient party (a) furnishes only that portion of the confidential information which the recipient party is, in the opinion of its counsel, legally required to disclose, and (b) uses its reasonable efforts to obtain reliable assurance that confidential treatment will be accorded the confidential information.

**Intellectual Property Rights:** An Order should not be used in connection with the creation of intellectual property. However, in the event there are services or work performed by Supplier pursuant to an Order that create any ideas, inventions or intellectual property rights capable of protection, such ideas and inventions shall be deemed works for hire and are the sole and exclusive property of RMR without requirement of any further payment hereunder. In the event it is determined RMR is not the owner of the intellectual property, Supplier hereby grants to RMR a fully-paid, royalty-free, transferable sublicense to make, have made, use, sell or offer for sale or import Products possessing such intellectual property.

**Patents and Trademarks:** Supplier shall defend, indemnify and hold harmless RMR against all claims or liabilities and expenses (including reasonable attorneys' fees) arising out of, or resulting from, the infringement of any intellectual property or other proprietary rights of any person including, without limitation, the infringement of any trademarks, trade names, trade dress, trade secrets, patents or the violation of any copyright laws or any other applicable federal, state or local laws, rules or regulations. In the event that any claim is made against RMR with respect to the foregoing, or in the event the Products is misbranded or bears illegal descriptive matter, RMR shall have the right, in addition to all other rights under contract or otherwise given by law, to cancel the Order for the Products, and any other Order with Supplier, and to return Products already delivered for full credit. In connection therewith, Supplier shall, at its sole expense, promptly undertake to procure for RMR the right to continue using such Products. If, however, such right cannot be procured on terms and conditions reasonably acceptable to RMR, Supplier shall, at its sole expense but at RMR's discretion: (a) promptly modify such Products to render it non-infringing but functionally equivalent or (b) refund to RMR the sums actually paid for the Products, and RMR shall cease to use same.



**No Publicity:** Supplier shall not make, nor permit any of their respective directors, officers, employees, agents, advisors, affiliates or representatives to make any press release, public announcement or other public disclosure with respect to the existence of an Order or this Agreement or the terms hereof without the prior consent of RMR.

**Representations and Warranties:** Supplier expressly represents and warrants that all Products furnished under the Order shall (a) conform to all Specifications and quality standards or requirements provided by RMR to Supplier, including, without limitation, the PPAP, and (b) be new and free from defects in material and workmanship. Supplier warrants that all such Products will conform to any statements made on the containers or labels or advertisements for such Products, and that any Products will be adequately contained, packaged, marked and labeled and, at the time RMR takes title to the Products, the Products shall not be adulterated, misbranded or otherwise in violation of the Federal Food, Drug and Cosmetic Act, 21 U.S.C.A., Section 301 et seq., as amended from time to time. Supplier represents and warrants to RMR that at the time of sale Supplier has good title to the Products, free and clear of all security interests, liens or encumbrances, and that no third party has any right, title or interest in the Products. Supplier represents and warrants that such Products shall be in material compliance with all applicable laws, rules, statutes and regulations governing the manufacture and sale of Products and the performance of its obligations under the Order. Supplier hereby represents, warrants and covenants that it currently does and it will continue to comply with all applicable international conventions relating to fair trade practices to which the United States and/or the country where the Products is produced are signatories, such as prohibitions against bribery, participation in secondary and tertiary boycotts and comparable conventions, as implemented in national law and regulation.

In the event that RMR has previously purchased conforming Products of the same description from Supplier, Supplier agrees that the Products to be delivered under the current Order shall be identical in all respects to the Products previously ordered. Supplier warrants that all Products furnished under the Order will be merchantable and will be safe and appropriate for the purpose for which Products of that kind is normally used. If Supplier knows or has reason to know the particular purpose for which RMR intends to use the Products, Supplier warrants that such Products will be fit for such particular purpose. Supplier warrants that Products furnished will conform in all respects to samples. Inspection, test, acceptance or use of the Products furnished under the Order shall not affect the Supplier's obligation under this warranty, and such warranties shall survive inspection, test, acceptance and use. Supplier's warranty shall run to RMR, its successors, assigns and customers, and users of Products sold by RMR. Supplier agrees to replace, or correct defects of, any Products not conforming to the foregoing warranty promptly without expense to RMR, when notified of such non-conformity by RMR, provided RMR elects to provide Supplier with the opportunity to do so. In the event of failure of Supplier to correct defects in or replace nonconforming Products promptly, RMR, after reasonable notice to Supplier, may make such corrections or replace such Products and charge Supplier for the cost incurred by RMR in doing so.

**Price Warranty:** Supplier warrants that the prices for the Products sold to RMR under the Order are not less favorable than those currently extended to any other customer for the same or similar articles in similar quantities. In the event Supplier reduces its price for such Products during the term of the Order, Supplier agrees to reduce the prices of the Order correspondingly. Supplier warrants that prices shown on the Order shall be complete, and no additional charges of any type shall be added without RMR's express written consent. Such additional charges include, but are not limited to drayage, shipping, packaging, labeling, customs duties and taxes, storage, insurance, boxing and crating. Payment terms date from receipt of material purchased or date of receipt of invoice, whichever is later.

**Exclusivity:** Supplier agrees that it shall not sell the Products made to RMR specification or RMR Customer specification to any of RMR's competitors.

**Insurance:** If the accomplishment of the Order requires or contemplates the performance of services or labor by Supplier's employees, or persons under contract to Supplier, on RMR's property, or property of RMR's customers, Supplier agrees that the persons doing such work shall not be considered employees of RMR. Supplier shall carry (a) Commercial General Liability Insurance in a minimum amount of US\$5,000,000 Combined Single Limit, Bodily Injury, and Property Damage, and (b) Products Recall insurance covering the actual costs sustained in recalling defective Products but



no event less than US\$1,000,000 per recall, in each case naming RMR as an additional insured. Insurance to be maintained by Supplier pursuant to the provisions of this section shall provide for written notice to RMR thirty (30) days in advance of any alteration, modification or cancellation of such insurance. All such policies of insurance shall contain a waiver of subrogation rights against RMR. Supplier shall furnish to RMR a certificate of insurance evidencing such coverage. Supplier shall defend, indemnify and hold harmless RMR from any and all claims or liabilities arising out of the work covered by this paragraph including all claims or liabilities arising out of the use of RMR's tools, equipment or other facilities.

**Indemnification:** Supplier shall defend, indemnify and hold harmless RMR and its distributors and customers from and against all damages, claims or liabilities and expenses (including reasonable attorneys' fees) arising out of, or resulting in any way from, any (a) defect in the Products purchased from Supplier under an Order; (b) the recall of the Products; (c) the recall of products into which the Products hereunder have been incorporated and/or combined, where such recall is the result of defects in the Products hereunder; (d) any third party claim for death, injury or property damage caused by the use or possession of the Products, except to the extent that such death, injury or damage results from the negligence or willful misconduct of RMR; (e) the label, labeling, promotional literature or other information concerning Products provided by Supplier; (f) the negligent act or omission or other wrongful conduct of Supplier; (g) the breach of any representation or warranty of Supplier, including those contained in this Agreement, the Order or created by operation of law; Products (h) Supplier's failure or alleged failure to warn, advise RMR of the need to warn, or adequately test the Products; and (i) the failure of the Products to meet RMR's Specifications, if any. This indemnification shall be in addition to the warranty obligations of Supplier and shall not be conditioned upon the waiver of any claims RMR may have against Supplier.

**Entire Agreement:** The Order, any documents referred to on the face thereof, and this Agreement constitute the entire agreement between RMR and Supplier with respect to the subject matter hereof.

**Force Majeure:** In the event of delay or temporary discontinuance of RMR's business in whole or in part by reason of fire, flood, tempest, earthquake, war, civil commotion, act of God, embargo, strike or other cause beyond RMR's control (a **Force Majeure Event**"), RMR may at its option, cancel any undelivered Order in whole or in part or delay delivery or acceptance occasioned by said causes. Supplier shall hold such Products at the direction of RMR and shall deliver it when the cause affecting the delay has been removed. RMR shall be responsible only for Supplier's direct additional costs in holding the Products or delaying performance of the Order at RMR's request. Supplier shall immediately give written notice of a Force Majeure Event to RMR. Any plant shutdowns for vacation or other reasons planned by Supplier requires at least three (3) months prior written notification to RMR.<sup>3</sup>

**Assignments:** The Order and any right thereunder is not assignable by Supplier, nor shall Supplier subcontract or delegate any portion or all of the Order, without the prior written consent of RMR, nor shall RMR be under any obligation to recognize any assignment of monies payable thereunder, nor of any rights in the Products ordered therein, nor of any other rights arising thereunder, or to pay any monies or deliver or return any Products ordered thereunder to any assignee without like consent. Notwithstanding the foregoing, RMR may assign an Order or any right thereunder to an affiliate without the written consent of Supplier.

**Waiver:** RMR's failure to insist on performance of any of the terms or conditions herein or in the Order on any one occasion, or to exercise any right or privilege, or RMR's waiver of any breach hereunder shall not thereafter waive any other terms, conditions or privileges, whether of the same or similar type, on any other occasion.

**RMR Policies:** Supplier shall comply with the (a) Trade Compliance Terms and Conditions, (b) Supplier Code of Conduct, (c) Supplier Manual, and (d) Information Security Requirements, as communicated to Supplier by RMR from time to time.

**Inspection of Records and Facilities:** All articles, materials and workmanship, as well as facilities where they are produced, will be subject to inspection and tests by RMR, RMR's customer, the FDA or RMR's or its customer's ISO Notified Body during manufacture and at all times and places to the extent practicable. Supplier shall provide and shall require all of Supplier's subcontractors to provide



full opportunity for such inspections in a manner acceptable to the inspectors. If an inspection or test is made on Supplier's premises, Supplier shall provide all reasonable facilities and assistance for the safety and convenience of the inspectors in the performance of their duties. In the event this Order is in excess of \$2,500, the duly authorized representatives of RMR, its applicable customer(s), and the government of the United States shall, until three (3) years after final payment under this Order or until such further time as may be designated in the applicable government regulations, have access to and the right to examine any pertinent books, papers, documents and records of Supplier involving manufacturing and quality assurance transactions related to this Order other than financial records. The Supplier agrees to retain in proper order for efficient retrieval, all such records for a period of fifteen (15) years. Supplier agrees to include in each subcontract Supplier might make hereunder appropriate provisions to the same effect. RMR shall have the right for itself and on behalf of its customers to audit Supplier and its suppliers with a minimum thirty (30) days' notice.

**Compliance with Laws:** Supplier shall be responsible for securing and maintaining any governmental or regulatory approvals necessary in order to manufacture and supply Products to the RMR. Supplier shall maintain any governmental or regulatory approvals necessary for its sale of the Products to the RMR. Supplier's facility where the Products are manufactured shall at all times remain compliant to Current Regulatory Standards and to current Good Manufacturing Practices per Title 21 Code of Federal Regulations ("CFR") Part 820. Supplier shall manufacture, label and package the Products in accordance with the Specifications, the PPAP and current good manufacturing practices as applicable under 21CFR820 and shall maintain suitable Production levels, based on RMR's forecasts to meet RMR's requirements of the Products.

Supplier agrees to obtain all necessary licenses or other authorizations as may be required for any and all items that it exports or re-exports under the Agreement. Supplier also agrees to provide such reasonable assistance as may be required to allow RMR to obtain such authorizations. Supplier also agrees not to export or re-export items to any entity, individual or destination that may be prohibited under applicable law. If at any time Supplier or Supplier's contract manufacturer is contacted by the FDA for inquiries or audits, Supplier shall notify RMR of any audit or impending audit by the FDA within one (1) business day of Supplier receiving notification and before audit is performed with specific reference to any of RMR's Products. Supplier shall also notify RMR immediately of any issues found during a FDA/notified body inspection that may impact the Products. Supplier shall be responsible for record retention of documentation generated at Supplier's site. Supplier shall provide RMR with copies of any FDA 483 reports or any similar reports relating to the Products or any facility in which the Products is manufactured. RMR reserves the right to have a representative onsite to represent RMR should the need arise. Supplier shall notify RMR in advance of any planned change in its current ISO or FDA registration status.

The Supplier, in performing the work required by the Order, represents and warrants that it shall comply with (a) the nondiscrimination provisions of Executive Orders 11246, 11141, 11625, 12138, 11758 and 11701, and any subsequent amendments thereof and to comply with the Rules and Regulations issued thereunder and agrees not to discriminate against any associate or applicant for employment because of race, religion, color, sex, age, national origin, handicap or veteran status; and (b) all applicable federal, state and municipal laws, regulations, codes, ordinances and orders, and any permit conditions as to which RMR has or should have knowledge, as the same may be in effect as of the time of the performance under the Order, including but not limited to full compliance with export and import laws, the U.S. Foreign Corrupt Practices Act, applicable provisions of The Health Insurance Portability and Accountability Act, Good Clinical Practice regulations (ICH-E6 Consolidated Guidance, April 1996), the Code of Federal Regulations (CFR), Title 21, Part 50, and any applicable data protection or privacy laws, rules, regulations and directives, including without limitation the requirements of Massachusetts General Laws c. 93H (Security Breaches) and the regulations promulgated thereunder including without limitation, 201 CMR 17.03 and 201 CMR 17.04 (Standards for the Protection of Personal Information of Residents of the Commonwealth) and the U.S. Department of Commerce Safe Harbor Privacy Principles with respect to the EU Directive of 24 October 1995 on the Protection of Individuals with Regard to the Processing of Personal Data and on the Free Movement of Such Data (European Union Data Protection Directive Safe Harbor), in each case as to the extent applicable to the particular Order.

The weights, measures, sizes, legends or words stamped, painted, branded or otherwise appearing on the Products or container, must comply in every respect with the laws, regulations, codes, ordinances and other requirements of the United States, and applicable local and state laws and regulations. Supplier also represents that by acceptance of the Order it has, and will continue, during the performance of the Order, to comply with the provisions of all other Federal, State



and local laws, and regulations from which liability may accrue to RMR from any violation thereof by Supplier.

**Validity of Agreement:** Each provision herein shall be deemed separate and distinct from all other provisions of this Agreement, and if any one of them or a portion thereof is declared illegal or unenforceable, it shall not affect the legality or enforceability of the other terms, conditions and provisions then remaining, and they shall continue in full force and effect.

**Applicable Law:** This Agreement, and any claim or controversy relating hereto, shall be governed by and interpreted exclusively in accordance with the laws of the Commonwealth of NEW YORK without giving effect to the conflict of laws principles thereof. RMR and Supplier hereto irrevocably submit to the jurisdiction of the state and federal courts situated within the Commonwealth of New York, city of Rochester, with respect to any disputes arising hereunder.

**Limitation on RMR's Liability—Statute of Limitations:** IN NO EVENT SHALL RMR BE LIABLE FOR ANTICIPATED PROFITS OR FOR INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES OF ANY KIND. RMR'S LIABILITY ON ANY CLAIM OF ANY KIND FOR ANY LOSS OR DAMAGE ARISING OUT OF OR IN CONNECTION WITH OR RESULTING FROM THE ORDER, THIS AGREEMENT OR FROM THE PERFORMANCE OR BREACH THEREOF SHALL IN NO CASE EXCEED THE PRICE ALLOCABLE TO THE PRODUCTS OR A UNIT THEREOF WHICH GIVES RISE TO THE CLAIM. RMR SHALL NOT BE LIABLE FOR PUNITIVE OR TREBLE DAMAGES OR OTHER PENALTIES OF ANY DESCRIPTION. ANY ACTION RESULTING FROM ANY BREACH ON THE PART OF RMR AS TO THE PRODUCTS DELIVERED HEREUNDER MUST BE COMMENCED WITHIN ONE (1) YEAR AFTER THE ACTUAL DATE OF SUCH BREACH-GIVING RISE TO THE ALLEGED CAUSE OF ACTION.

Rev. August 21, 2018