1.0 INTRODUCTION:
Genicon, INC (the “Company”) located at 6869 Stapoint Ct Suite 114 Winter Park, FL 32792, has created these
Standard Terms and Conditions, which apply to the purchase of all equipment, goods and services, including the
repair or evaluation of medical or non-medical equipment or devices, unless otherwise stipulated in a separate
Agreement or amended to the Purchase Order.

2.0 AFFILIATES:
Upon request, prices charged on the Purchase Order may be extended to any current or future Affiliate of the
Company.

3.0 ASSIGNMENT/TRANSFER OF PURCHASE ORDER:
The Vendor will not assign nor transfer this Purchase Order in part, or in whole, to any other Vendor, without the
express written approval of the Company.

4.0 AUDIT:
Authorized Company employees and/or their agents have the right to review the records and accounts maintained by
the Vendor pertaining to:
4.1 Service levels;
4.2 The pricing of products and services related to any established pricing formulas;
4.3 The pricing of products and services related to agreed benchmarks and/or most favored customer pricing
arrangements; and
4.4 Source documents supporting invoices to the Company.
4.5 Inspections required under FDA, ISO, or other authoritative body.

5.0 CANCELLATION:
The Company reserves the right to cancel a Purchase Order. Reasons for cancellation can include, but are not
limited to, vendor performance, product performance, product quality, product discontinuation, products affected by
changes in clinical practices and non-compliance to the Standard Terms and Conditions of the Purchase Order.

6. WARRANTIES AND COMPLIANCE WITH LAWS
6.1 Vendor expressly warrants that all Products provided pursuant to this Purchase Order shall be: (i) merchantable;
(ii) fit and safe for the purpose for which it is manufactured; (iii) free from defects in material and workmanship; (iv) in
conformance with applicable specifications, drawings, samples and descriptions; and (v) that if of Vendor’s design,
shall be free from design defects.
Additionally, Vendor warrants that it has good title to the Products supplied and that they are free and clear from all
liens and encumbrances. These warranties shall survive acceptance and payment by the Company. Products not in
accordance with these warranties may be returned to Vendor and Vendor shall pay for transportation both ways. The
Company shall have the option of returning such Products to Vendor at any time after delivery for credit or
replacement at the price charged. The foregoing shall not be in limitation of any rights which the Company may have
at law or in equity by reason of any breach of warranties.
6.2 Vendor hereby guarantees that the Products sold hereunder are not and will not be, on the date of shipment or
delivery, either adulterated or misbranded within the meaning of the U.S. Food, Drug, and Cosmetic Act, as
amended, or within the meaning of any applicable state or local law in which the definitions of adulteration and
misbranding are substantially identical with those contained in the Federal Food, Drug, and Cosmetic Act, as said act
and such laws are constituted and effective at the time of such shipment or delivery, and that such Products are not
and will not be, on the date of such shipment or delivery, Products which may not, under the provisions of Section
404 or 505 of said Act, to be introduced into interstate commerce.
6.3 Vendor warrants that the Products purchased or provided hereunder have been produced and/or have been
designed to and will comply fully with all applicable laws, regulations and standards in effect in the US and in the
country(s) in which the Products are manufactured or assembled, on the date of shipment, including, without
limitation, the appropriate sections of the US Occupational Safety and Health Standards Act and the US Fair Labor
Standards Act, as amended, and the equivalent legislation in effect in the country(s) in which the Products are
manufactured or assembled.
6.4 If this Purchase Order is issued pursuant to a contract with the United States Government, or any agency thereof,
and such fact is communicated to Vendor on this Purchase Order form or otherwise, then: (i) Vendor agrees to allow
access to any representative of the United States Government, or any agency thereof, to Vendor’s plants, materials
and process, and relevant books and records; (ii) all materials and workmanship is subject to inspection by the
Government, and the Government, as well as The Company, has the right to reject any Products found to be non-
conforming or defective; and (iii) Vendor performing work under this Purchase Order shall not discriminate against
any employee or applicant because of race, creed, color, national origin or sex and shall include a similar clause in its
subcontracts.
6.5 The following are hereby incorporated by reference and made a part of this Purchase Order as is fully set forth
herein: (i) the provisions of the Equal Opportunity clause set forth in 41 CFR 60-1.4(a) pursuant to the requirements
of Executive Order 11246; (ii) applicable contractual requirements of the Rehabilitation Act of 1973 as set forth in 41
CFR 60-741.4; (iii) applicable contractual requirements of the Vietnam Era Veterans Readjustment Assistance Act of
1974 as set forth in 41 CFR 60-250.4; (iv) applicable contractual provisions of Public Law 95-507 concerning the
utilization and employment of Small Business, Small Disadvantaged Business and Women-Owned Business
Concerns; and (v) any law, order or regulatory provision issued in addition, supplement or replacement of the
foregoing concerning federal contractors.
7.0 CONFIDENTIALITY AND PRIVACY:
7.1 The Terms and Conditions of the Purchase Order are confidential to the Company and the Vendor, and are not to
be disseminated, distributed, or otherwise conveyed to third parties, other than those officials and employees of
either party whose duties require knowledge thereof, without the expressed written consent of both parties, except in
the pursuit of legal redress in the courts of law or in pursuit of the direction of any legal authority.
7.2 Vendors are required to comply with Federal Health Information Protection Act (HIPA) where relevant, and
Confidentiality Requirements for Suppliers, posted on the Company’s web site.
8.0 DELIVERY:
Failure of the Vendor to deliver the goods and/or services in accordance with the specified delivery date(s) listed on
the Purchase Order may give cause for the Company to cancel the Purchase Order without penalty. Additional
charges as a result of the Vendor using a non-preapproved shipping method will be covered by the Vendor.
Preapproved shipping methods must be in writing if different than what is on Purchase Order.
9.0 ELECTRONIC COMMERCE:
Where applicable, the Vendor agrees to work with the Company to provide full E-Commerce functionality and
connectivity with the Company to process all business transactions, which will include, but not limited to: purchase
order, order acknowledgement, e-invoice, e-catalogue and advance ship notice. Should the Vendor not currently
have any of the above capabilities, the Vendor and the Company agree to develop strategies and timelines for
implementation to the mutual acceptance of both parties.
10.0 FREIGHT CHARGES:
All orders will be shipped prepaid F.O.B. the Company, unless otherwise negotiated.
11.0 FURNISH AND INSTALL:
Any equipment on the Purchase Order will be provided on a Vendor furnish basis. The Vendor will have complete responsibility for the equipment until it is in place and working. Any special installation preparation and requirements must be submitted to the Company. All transportation and coordination arrangements will be the responsibility of the Vendor. Delivery of equipment will be coordinated so that items will be delivered direct to the installation site or as specified by the Company.

12.0 INDEMNIFICATION:
12.1 The Vendor shall indemnify and hold harmless the Company, and Affiliates, its directors, officers, employees, volunteers and agents from and against all liabilities, claims, demands, losses, costs, expenses, (including reasonable legal fees) or damages, accidents, suits and/or proceedings (hereinafter called claims) occasioned wholly or in part, 12.1.1 by the negligent acts, errors and omissions by the Vendor, its officers, directors, employees, agents or others for whom it is responsible in law, to persons or property arising out of or attributable to the use of the Vendor’s equipment, products and/or services by The Company. Such claims are attributable to bodily injury, sickness, personal injury, death or damage to or destruction of property; or
12.1.2 as a result of anything done or permitted to be done by the Vendor, its directors, officers, employees, agents or others for which they are responsible by law, or in pursuit of the Purchase Order.

13.0 INSURANCE AND LIABILITY:
13.1 Upon issuance of the Company Purchase Order, the Vendor shall provide proof of its current Commercial General Liability Insurance Policy and agrees to maintain coverage through the life of the Purchase Order. The Vendor shall carry insurance for not less than $1,000,000 (inclusive coverage) for bodily injury including death, personal injury, and/or property damage. The Company at its discretion may request the policy be endorsed to include the Company and Affiliates as additional insureds’ or loss payee.

13.2 Automobile liability insurance in respect of licensed vehicles shall have limits of not less than $1,000,000 (inclusive per occurrence) for bodily injury, death, and damage to property, covering all licensed vehicles owned or leased by the Vendor/Contractor.

13.3 The Vendor agrees to provide proof of liability insurance by providing a current valid certificate of insurance to the Company the term of the Purchase Order.

13.4 The Vendor must advise the Company immediately of any change in insurance provider or limits of liability. Failure to comply with the insurance requirements will result in the cancellation of the Purchase Order.

14.0 INVOICES:
Unless otherwise stated, direct all invoices, with Purchase Order Number, for payment to:
GENICON
6869 Stapoint Ct, Suite 114
Winter Park FL 32792

15.0 NEWS RELEASE:
The Vendor shall not issue any publicity or news release pertaining to the Purchase Order, without prior written approval from the Company.

16.0 PAYMENT TERMS:
Payment terms are net 30 days unless otherwise specified on Purchase Order.
17.0 PRICING:
17.1 The Vendor agrees that the Company will receive the best available pricing based on accounts of similar size and volumes. Failure on the part of the Vendor to address this issue may be considered just cause for cancellation of the Purchase Order.
17.2 Unless otherwise stipulated in a separate Agreement or amendment to the Purchase Order, the Vendor agrees to provide the Company with a minimum sixty (60) days advance written notice of any price increases. The Company reserves the right to negotiate these price increases to the mutual acceptance of both parties.

18.0 QUALITY:
18.1 All medical and surgical supplies must be FDA approved for Hospital use as well as abide by all applicable standards of ISO13485.
18.2 Products must be latex free. The Vendor must declare the latex content of all their raw materials.
18.3 All goods delivered will be inspected and tested by the Company as soon as possible after delivery and if found unsatisfactory will be returned to the Vendor for full and immediate credit.

19.0 RESTOCKING CHARGES:
The company policy is not to accept restocking charges for equipment or goods returned to the Vendor for any reasons unless otherwise negotiated.

20.0 SHIPMENTS
20.1 All items shall be securely and properly packed for shipment according to accepted standard commercial practice, without extra charge for packing materials or containers. The containers will remain the property of the Company unless otherwise stated. Where materials are shipped in refillable containers which may require a rental charge, this rental charge must be shown separately and not be included in the unit cost of the item.
20.2 Current Material Safety Data Sheets (MSDS) must be provided for all products covered by Occupational Safety and Health Administration.
20.3 Packing slips, in duplicate, must accompany each shipment.
20.4 Purchase Order Numbers must be shown on all shipping documents, packing slips, invoices and labels, etc.
20.5 Goods must be packaged and transported in accordance with the laws of the United States and current relevant legislation.
20.6 All perishable goods must be packaged to withstand 72 hours in transit.
20.7 The Company, will not be held liable for consequential costs arising from the improper consignment of goods.
20.8 It is the Vendor’s responsibility to declare the full value of the order on their carrier’s Bill of Lading.

21.0 SHIPMENTS FROM OUTSIDE United States:
21.1 The Company Customs Broker is based upon shipping method.
21.2 All documents must reference the Purchase Order Number.
21.3 Commercial documents must accompany all shipments to United States, to include a fully completed United States customs invoice or commercial invoice. Mandatory fields include country of origin, currency of sale, price paid or payable, complete description of the goods purchased, consignee, and exporter.
21.4 Shipping terms must be indicated on all documents.
21.5 Vendor must include their Federal Tax ID # on all documents.
21.6 On all documentation for repairs, indicate if the item(s) are under warranty and the value of the repairs.
21.7 In the event that an incorrect description or incomplete or inaccurate description result in a Penalty being applied by United States customs, the amount of this penalty may be charged back to the Vendor.

22.0 SITE RULES FOR CONTRACTORS:
22.1 Contractors and sub trades are required to comply with all applicable Federal, State and Municipal laws and Regulations.
23.0 TAXES:
Upon request we can provide our State of Florida Sales Tax number

24.0 NON COMPETE:
During the period of time we have a commercial relationship and for a period of one (1) year from the date of that commercial relationship terminates, the Parties agree that they shall not, directly or indirectly, solicit, encourage, entice or induce employees or consultants to leave the employment or retainer of the other Party or any of its affiliates. Provided that this restriction shall not prevent general advertising of employment opportunities not specifically directed to employees or consultants of the other Party.

Addendum Attached
Addendum to Terms and Conditions of Purchase

Confidentiality and Non-Disclosure

All confidential and/or proprietary information of the Parties including, but not limited to, information relating to any Product or the business affairs or finances of either Party, shall be held in confidence and not disclosed by the other Party to any third party or used, for any reason whatsoever, outside the scope of this Agreement; without written approval of the other Party.

This Clause shall survive for five (5) years from the expiration or termination of this agreement.

In connection with the Product and during the course of the Parties’ business discussions or dealings, each Party may disclose or provide to the other Party, and the other Party may have access to, and may become acquainted with, such Party’s technical and business data, products and product descriptions, research data and status of developmental efforts, pricing information, services, customers, suppliers, manufacturers, methodologies, technologies, processes, data bases, business plans, strategies, financial data, trade secrets, contracts and other information and materials (“Confidential Information”). Confidential Information may include tangible and intangible documents and materials and may be disclosed orally, visually, in writing or through other media, including, without limitation, videotape, electronically-recorded data on diskette, and data transmitted electronically. The Parties agree that, where practical, all information furnished pursuant to this Agreement, which the disclosing Party intends to be considered Confidential Information shall be marked with a confidential or proprietary notice. Any oral disclosure shall be identified as being Confidential Information at the time of disclosure and confirmed in writing within ten (10) calendar days thereafter.

Each Party shall hold and maintain all Confidential Information of the other Party in confidence, and neither Party shall disclose, permit the disclosure of, or make available any Confidential Information of the other Party to any third party without the prior written consent of the Party that provided such Confidential Information.

Each Party shall restrict disclosure of such Confidential Information to its employees, advisors, agents, representatives, and contractors with a need to know who have agreed to protect and preserve the confidentiality of such disclosures. This Agreement does not grant or imply any right or license to use GENICON’s Confidential Information except as set forth in this Agreement.

Each Party shall exercise reasonable care under the circumstances or the same degree of care that it exercises with respect to its own Confidential Information to prevent disclosure of the other Party’s Confidential Information to any third party, whichever standard of care is greater.

On request of the other Party, each Party shall return to it all written or other tangible materials and all copies thereof that contain or refer to the other Party’s Confidential Information.

Post Market Surveillance and Traceability

The manufacturer agrees to maintain and track all post market surveillance. Manufacturer will provide the surveillance data upon GENICON’s request. GENICON agrees to maintain traceability on all products provided by the manufacturer that are distributed by GENICON. Manufacturer agrees to supply GENICON with their findings from any Post Market Investigations. Manufacturer will address all CPARs and NCMRs within the requested timeframe.

Document Retention
The manufacturer agrees to maintain all documentation related to the production, quality control and distribution of product for five (5) years or the life of the product, whichever is longer. All documentation regarding quality control will be provided to GENICON upon GENICON’s request. GENICON agrees to maintain all documentation related to distribution of the product for five (5) years or the life of the product, whichever is longer.

**Documentation Agreement**

Manufacturer will provide to GENICON the entire Technical File for any product(s) provided to GENICON. The technical file must include but is not limited to:

- Essential Requirements Checklist
- ISO9001 and/or ISO13485 Certificates
- FDA Registration, Device Listing Information
- 510K, if applicable
- CE Certificate(s)
- Declaration of Conformity
- Clinical studies/evaluation
- Baseline inspection criteria
- Sterilization Validations including certificates of compliance
- Shelf life studies with performance evaluation (real or accelerated)
- Labels for pouch, shelf box, carton (include barcode capability)
- Instructions for Use in English
- All applicable test reports (ISO10993, ISO60601, etc.)
- Material descriptions and certificates for all materials
- Failure Mode and Effects Analysis
- Installation, maintenance, and servicing processing and methods, as applicable
- Product Classification Rationale
- List of Harmonized Standards
- Top Level Drawings
- Packaging Evaluation

Manufacturer will provide updated documents as necessary. Documents may be provided electronically. Regulatory Authorities will be granted full access to the Technical Documentation.

**Auditing Agreement**

The manufacturer agrees to notify GENICON of any significant changes in design to the product prior to implementation as well as prior to updating the OBL technical file. All updates to the technical file will be provided to GENICON.

Manufacturer will accommodate an unannounced audit by GENICON’s Notified Body in accordance with current standards.

**Revision History**

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Page 7 of 8
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