BVI
General Terms and Conditions of Sale

1. General

These General Terms and Conditions of Sale (“Terms and Conditions”) shall apply to and govern the sale of products ("Products") by Beaver-Visitec International Sales Limited or any of its affiliates as identified in the relevant purchase order and invoice (“BVI”) to the buyer identified in the relevant purchase order and invoice ("Buyer") to the exclusion of all other terms and conditions including any terms and conditions which Buyer may purport to apply under any purchase order or similar document or which could be implied by trade custom, practice or course of dealing. BVI objects to other terms and conditions that may be proposed by Buyer. Any variation to these Terms and Conditions (including any special terms agreed between the parties) shall be inapplicable unless agreed in writing by BVI.

No particulars, statements or descriptions, whether contained in any advertising matter, catalogues, brochures, price lists or otherwise provided by BVI concerning the Products, nor any oral representations by any employee, agent or representative of BVI shall form part of the agreement between the parties (including these Terms and Conditions) or be treated as a representation on the part of BVI.

2. Orders

By placing an order, Buyer warrants that it is in compliance with and respects all applicable laws and regulations regarding the purchase, importing, delivery and sale of the Products and that it holds any and all authorization or license whatsoever required by applicable regulation and complied with any requirement required by applicable regulation for the use and possession of the Products. Once placed, the order is binding on Buyer and cannot be cancelled by it without the written consent of BVI. No order will be deemed binding on BVI unless and until BVI issues a written acceptance of such order. BVI, at its discretion, may cancel an accepted order by serving written notice to Buyer in the event that: (i) Buyer fails to properly fulfil any of its obligations hereunder, which failure is not cured within fifteen (15) days of BVI's written notice thereof (if capable of being cured); (ii) Buyer violates any of the representations, warranties or covenants contained in Section 9 of these Terms and Conditions; (iii) Buyer assigns any of its property for the benefit of creditors, or in case Buyer (or any other party) applies for the appointment of a trustee or receiver of any parts of its assets, or commences any proceedings under any bankruptcy, reorganization, arrangement, insolvency, readjustment of debt, dissolution, or other liquidation law of any jurisdiction; or (iv) in case of bankruptcy, liquidation, insolvency or suspension of payments of or by Buyer. BVI's right to cancel an accepted order on Buyer's default is without prejudice to BVI's right to claim additional damages, or any other rights BVI may have (including the right to suspend its own obligations towards Buyer).

3. Prices, fees and payments

All prices and other fees hereunder are exclusive of any tax, levy, import duties or similar governmental charge (including VAT taxes, excise taxes, and sales and use taxes) that may be assessed by any jurisdiction, whether based on gross revenue, the delivery, possession or use of the Products. BVI reserves the right to change prices at any time. Additional freight/delivery charges are applicable for certain Products or quantities of Products.

Unless expressly agreed otherwise in writing, payment for all Products purchased hereunder shall be made in advance by direct internet bank transfer. Where BVI agrees in its sole discretion to supply the Products on credit, the Products shall be paid for not later than the agreed terms. BVI reserves the right to close the account or withhold further supplies of Products if Buyer fails to settle the invoice by its due date, without prejudice to any existing rights BVI may have in respect of any such unpaid invoice. Any credit terms or extension of credit allowed to Buyer by BVI may be changed or withdrawn at any time. Time shall be of the essence for the purposes of this Section 3 only. If in the opinion of BVI, the credit-worthiness of Buyer deteriorates before delivery of the Products, BVI may require full or partial payment of the price prior to delivery of the Products or the provision of security for payment by Buyer in a form acceptable to BVI. BVI will notify Buyer of this requirement.

Non-payment, when due, of a single invoice shall render the outstanding balances on all the other invoices recoverable immediately, even those that have not fallen due yet. Interest on late payments shall accrue daily and compound monthly at the one (1) month EURIBOR interest rate plus three percent (3%) per annum, without being less than five (5) %, but in no event to exceed the highest lawful rate of interest, calculated from the date such amount was due until the date payment is received by BVI.

Buyer may not set-off, deduct or withhold payment of any amount due to BVI because of any counter-claim, abatement, or other reason, whether arising from breach of contract, tort (including negligence), breach of statutory duty or any other matter whatsoever in order to justify withholding payment of any such amount in whole or in part.

4. Delivery, risk and title

4.1 Delivery of the Products

Unless expressly agreed otherwise in writing, Products are delivered Ex Works (Incoterms 2020) BVI's warehouse. Delivery dates or lead times are intended as estimates only and shall not be of the essence. BVI shall not be liable in any way for any direct or indirect loss, damage or expense (including loss of profits and liability to third parties) suffered or incurred by Buyer as a consequence of any delay in delivery. All visible defects or discrepancies (shipping, shortages, overages, missing documents, damages, pricing, billing charge etc.) are to be reported within eight (8) calendar days of physical delivery date via phone call, email and/or debit memo notification. Failure to provide notification within eight (8) calendar days of the physical receipt will be ground for denial of the claim.

4.2 Risk and title

Risk in the Products shall pass to Buyer on delivery. Title, property and ownership in the Products, notwithstanding delivery of the Products to Buyer, shall not pass from BVI until (a) Buyer shall have paid BVI in full for the Products (including any

transportation charges, taxes and late payment interest, if any); and (b) no other sums are then outstanding from Buyer to BVI on any account whatever whether or not such sums have become due for payment.

While property in the Products remains with BVI pursuant to this Section, Buyer shall hold the Products on a fiduciary basis only and as bailee for BVI. Buyer shall store the Products separately from its own products and those of any other person in good condition and marked in such a way that they are clearly identifiable as the property of BVI and shall insure the Products to their full value against "All Risks" to the reasonable satisfaction of BVI. In the event that BVI is entitled to exercise any of its rights under this Section 4.2, any right of Buyer to sell, dispose of, deal or in any way use Products in which the property remains vested in BVI shall cease forthwith. Buyer shall immediately place any of the Products in its possession or under its control at the disposal of BVI and BVI shall (without prejudice to any of its other rights and remedies) have the right to re-possess and use such Products and may together with its servants or agents, enter upon any land or building, vehicle or vessel or other place upon which such Products are reasonably thought to be situated for the purpose of removing any such Products. For the purpose of so taking possession Buyer gives to BVI irrevocable authority to enter its premises without notice for the purpose of collecting and removing the Products. Notwithstanding the foregoing, Buyer may use the Products in the ordinary course of its business, but may not otherwise deal with, use, sell, part with possession of, consume or otherwise dispose of the Products until title to them has passed to Buyer as aforesaid. Any sale by Buyer permitted by this Section as between Buyer and its customer, shall be effected by Buyer as principal and not as agent, but as between Buyer and BVI, Buyer shall have a fiduciary duty to account to BVI for the proceeds of any such sale up to the total amount outstanding to BVI as aforesaid, and pending such accounting shall hold the same on trust for BVI.

5. Warranty

5.1 General

Except as expressly provided in this Section 5, all warranties, conditions, representations, indemnities and guarantees with respect to the Products, whether express or implied, arising by law, custom, prior oral or written statements by BVI or otherwise (including, but not limited to any warranty of merchantability, non-infringement, or fitness for a particular purpose) are hereby overridden, excluded and disclaimed. Notwithstanding anything to the contrary herein, the following defects will in any event not be covered by any warranty hereunder:

(a) defects due to mishandling during shipping (to the extent the shipping of the Products is at Buyer's risk) or storage, or defects due to use that does not comply with (i) applicable laws and regulations, (ii) the instructions provided by BVI, (iii) the information in the Product instructions and/or on its packaging. The identity of the person who did not follow these instructions (Buyer or a third party) is irrelevant;

(b) defects that did not exist at the time of delivery and/or that are the result of normal wear and tear on the Products, or that are the result of deterioration or accidents caused by carelessness, abuse or clumsiness, or lack of maintenance of the Products.

Without prejudice to the warranty terms of the respective Products as set out below, Buyer's sole and exclusive remedy, and BVI's sole obligation in satisfying Buyer's claims for defects under the respective warranties, shall be to replace or, at BVI's sole discretion, grant Buyer a credit for such returns against future purchases.

5.2 For BVI, Vitreq and ARCAD Products

For all BVI, Vitreq and/or ARCAD Products to be delivered to Buyer pursuant to these Terms and Conditions (excluding Endo Optiks® Ophthalmic Micro Endoscopes, which are subject to the paragraph (**) below), BVI represents and warrants that the Products shall be free from material defects in materials and workmanship for one (1) year from the date of purchase. The foregoing warranty shall be void if the Product has been misused, neglected, improperly stored or handled, altered, abused or used for any purpose other than the one for which it was manufactured or if the Product's failure to conform to the foregoing warranty was due in whole or in part to other conditions beyond the control of BVI. Buyer must notify BVI of any (latent) defect within eight (8) days after Buyer could have reasonably discovered the defect. Any replacement Products shall be at BVI's option. This warranty is not transferable and is subject to limitations herein.

(**) For all Endo Optiks® Products to be delivered to Buyer pursuant to these Terms and Conditions, the one (1) year warranty set forth in above is only applicable to Endo Optiks® systems and accessories, and does not include the Endo Optiks® Ophthalmic Micro Endoscopes. The Endo Optiks® Ophthalmic Micro Endoscopes have a warranty against (latent) manufacturing defects, not including ordinary wear and tear, for four (4) or fewer uses. Buyer must notify BVI of any (latent) defect promptly after Buyer could have reasonably discovered the defect. Damage or defect at any time to the Endo Optiks® Ophthalmic Micro Endoscopes, within the four (4) uses, from wear and tear, cleaning, sterilization, misuse, improper storage or handling, negligence, accident, abuse or unsuitable or abnormal maintenance will immediately void this warranty. Any returned Products will be subject to inspection and will be determinative of usage. All ENDO OPTIKS® Ophthalmic Micro Endoscopes must be sterilized by the user before returning to BVI. For Endo Optiks® Endoscopy Systems, the following are not covered by this warranty: (i) onsite service for any component or part of the Endo Optiks® system which fails due to user error; and (ii) preventative maintenance.

BVI will repair and/or exchange parts for the Endo Optiks® Endoscopy Systems/Products in accordance with the terms of the applicable warranty. During the applicable warranty period, such repairs and/or replacements shall be free of charge for manufacturing defects only. However, if the warranty period has expired or such repairs are not covered by the warranty, there will be a fee for the repairs, including parts and labor. A loaner unit will be provided upon request during the covered period while the warranted unit has been returned for repair. Ground shipping on warranted systems will be covered by BVI.

5.3 For Optikon Products

1. BVI warrants that all Optikon Products to be delivered to Buyer pursuant to these Terms and Conditions have been manufactured in accordance with the ISO 9001 and ISO 13485 standards, and comply with the Medical Devices Directive as

amended, and when applicable, the Medical Devices Regulation, at the time of shipment. This is the sole warranty for Optikon Products not covered by point 2 of this Optikon Products Warranty.

2. For all Optikon Products except for (i) Optikon consumables and (ii) Optikon Products for which the product documentation provides for different warranty terms, BVI shall provide a warranty to Buyer warranting that such Products shall be free from (latent) defects in material or workmanship for a period of twelve (12) months from the date of the invoice (the "**Optikon Warranty Period**"). The warranty on consumable materials is limited to the first use. The warranty includes the research for causes of defects, reparation of the defect and a final inspection of the unit, or part(s). For the avoidance of doubt, Buyer shall have no claim against BVI for any defects in the Products after expiration of the Optikon Warranty Period. Buyer must notify BVI in writing of any (latent) defects in the Products within a period of eight (8) days after Buyer could have reasonably discovered the defect.

(a) All items under warranty pursuant to this point 2 of this Optikon Products Warranty shall be repaired or replaced by BVI, where necessary, free of charge.
(b) This warranty does not cover the results of misuse, accidents, abuse, tampering or any alteration by anyone, other than BVI's authorized personnel.
(c) BVI reserves the right to ascertain whether the defective Products have been altered, tampered with, in any way, or have been damaged by improper use. The opinion of BVI's laboratory shall be binding upon the parties.
(d) No warranty shall be recognised if:
    (A) the serial number of the Products attributed by BVI is missing, tampered and/or not clearly readable;
    (B) payment has not been effected in accordance with the payment conditions;
    (C) Buyer has not notified BVI in writing of any (latent) defects in the Products within eight (8) days after Buyer could have reasonably discovered the defect.
(e) The warranty does not include expenses for return shipment of the Products. All expenses in relation to transport and packing shall be borne by Buyer, except in the event of a (latent) defect.
(f) In case of a requested intervention by BVI's technicians, all travel and hotel expenses shall be debited to Buyer.
(g) BVI cannot be held liable for any damage caused to the Products during the transportation of the Products.
(h) BVI shall only be liable for safety, reliability and performance issues if:
    (A) upgrades, calibrations and repairs have been carried out by BVI's authorized personnel; and
    (B) the main electric installation to which the console is connected complies with the I.E.C. or UL safety standards.

5.4 For PhysIOL Products
BVI warrants that PhysIOL Products to be delivered to Buyer pursuant to these Terms and Conditions have been manufactured in accordance with the ISO 9001 and ISO 13485 standards, and comply with the EU Medical Devices Directive as amended, and when applicable, the EU Medical Devices Regulation, at the time of shipment. This warranty is the sole warranty given by BVI to Buyer relating to such Products and is exclusive of any other warranty or remedy, whether expressed or implied.

Buyer will notify BVI of any (latent) defects, within eight (8) days from the date Buyer becomes or should have reasonably become aware of such defects. If BVI is responsible for such defect, the defective Products will be either replaced or, at the option of BVI, refunded by BVI. Such replacement or refund shall be Buyer's sole and exclusive remedy in case of the shipment by BVI of nonconforming Products. BVI shall have no liability whatsoever to Buyer in respect of any alleged defects in the Products unless it is notified of such defects within the period set out in this Section. Failing to do so, Buyer shall be deemed to have accepted the Products.

6. Expiration of Products
Buyer shall no longer use, and shall see to it that its customers will no longer use, any and all Products for which the validity period specified in the labelling of the Products has expired.

7. Traceability, Storage, Complaints and Adverse Events
Buyer shall keep all stocks of the Products that it holds in conditions appropriate for their storage, including by complying with any storage or handling guidelines as BVI may provide from time to time as well as guidelines and recommendations issued by the health authorities applicable in the territory in which the Products are used, and to establish and maintain procedures for the control of storage areas and stock rooms for Products to prevent mix-ups, damage, deterioration, contamination, temperature or other adverse effects pending use or distribution and to ensure that no obsolete, rejected, or deteriorated Product is used or distributed. With respect to each of the respective Products, Buyer shall comply with the obligations and rules relating to traceability and storage thereof, as communicated by BVI from time to time.

Buyer shall immediately and no later than within two (2) days of Buyer's receipt or knowledge, report customer complaints and adverse events to BVI through normal channels for resolution and to BVI's Quality Assurance Department. Buyer's report to BVI shall include a copy of all communications with the customer or relevant third party. Complaints may take the form of failure to meet BVI specifications, quality, durability, reliability, safety, effectiveness, or performance. If requested by BVI in writing, Buyer shall use its best efforts to procure the Products that have, or have possibly been, the cause of a customer complaint/adverse event and return said Products to BVI to permit BVI to perform an evaluation of the Products . The steps taken by Buyer in such circumstances shall be detailed in writing to BVI. Buyer shall consult with BVI before taking any steps in response to any complaint or adverse event. Where a corrective action is determined to be necessary Buyer shall, when so requested in writing, assist BVI in the execution of such action.

Buyer agrees to cooperate and assist BVI in a reasonable manner in any recall actions in respect of the Products and to follow any reasonable guidelines or instructions issued by BVI in connection therewith.

8. Liability
8.1. Except as expressly stated in these Terms and Conditions, BVI does not give any representations, warranties or undertakings in relation to the Products or in relation to the performance of its obligations under these Terms and Conditions. Any representation, condition or warranty which might be implied or incorporated into these Terms and Conditions by reason of statute,

common law or otherwise is excluded to the fullest extent permitted by law.

8.2. Under no circumstances will BVI, its agents or licensors be liable to Buyer or any other person for any loss of income, loss of actual or anticipated profits, loss of business, loss of contracts, loss of goodwill or reputation, loss of anticipated savings, loss of marketing commitments, loss of data, goodwill, use of money, or use of products, interruption in use or availability of data, stoppage of other work or impairment of other assets or any type of *lucrum cessans* or any consequential, indirect, special, punitive, or incidental damages, whether foreseeable or unforeseeable, based on claims in contract (including grave fault), tort or otherwise arising out of or in connection with these Terms and Conditions or any separate contracts thereunder, the sale of Products, or performance of the deliverables resulting therefrom.

In no event shall the aggregate liability to Buyer or any other person which BVI and its agents or licensors may incur, whether foreseeable or unforeseeable, based on claims in contract (including grave fault), tort or otherwise arising out of or in connection with these Terms and Conditions, the sale of Products or the use of the Products, exceed, as applicable, the total amount actually paid to BVI by Buyer for the applicable Product that caused the damage, or (ii) the total amount paid to BVI by Buyer pursuant to these Terms and Conditions in the twelve (12) months prior to the event(s) giving rise to any claim for damages.

8.3. Nothing in these Terms and Conditions shall restrict or exclude BVI's liability for death or personal injury caused by BVI's negligence or the negligence of its employees or sub-contractors or any other liability which may not be lawfully excluded or limited.

8.4. The parties confirm that the provisions on liability as set out in this Section 8 are indivisibly connected to the pricing and remuneration provisions in these Terms and Conditions. Parties expressly acknowledge that without these provisions they would not have concluded these Terms and Conditions with these pricing and remuneration provisions.

9. Compliance

9.1 General

Buyer covenants and agrees that all of its activities performed, directly or indirectly, in connection with these Terms and Conditions shall be carried out in compliance with all applicable laws, regulations, ordinances, rules, industry standards, codes of conducts, best distribution practices, guidelines and regulations of any governmental or regulatory authority having jurisdiction over Buyer and/or its activities.

Buyer's furthermore covenants and agrees that its use of the Products must comply with any and all rules applicable to its profession. Buyer must therefore not alter its conduct as a healthcare institution or professional for the purpose of obtaining benefits under these Terms and Conditions. In this respect, Buyer represents and warrants that its acceptance of these Terms and Conditions is not in exchange for any explicit or implicit agreement or understanding that Buyer will purchase, lease, order, prescribe, recommend or otherwise arrange for the use of Products, except as set out herein.

9.2 Export controls and sanctions

Buyer represents and warrants its understanding that any Products, or related technical information supplied to Buyer in accordance with these Terms and Conditions, may be subject to the jurisdiction of the export control and economic sanctions laws and regulations of the U.S., including but not limited to the United States Export Administration Regulations ("**EAR**") set forth in 15 C.F.R. §730-774 and the economic sanctions programs as set forth in 31 C.F.R. §500-598 and certain executive orders, the European Union, the United Kingdom, Ukraine and/or of other countries or international organizations (collectively, "**Trade Control Laws"**). Buyer shall take no action that violates, or would cause BVI to be in violation of, the Trade Control Laws.

Buyer shall not re-import into the United States without BVI's specific written authorization. In the event such authorization is granted in writing by BVI, Buyer shall (i) comply strictly with all applicable requirements of the Trade Control Laws and any other applicable export control requirements and (ii) cooperate fully with BVI in any official or unofficial audit or inspection that relates to these controls, including, but not limited to, making available to BVI such of Buyer's records that BVI may reasonably request to confirm Buyer's compliance with these controls.

In no event shall Buyer export, re-export, divert, transfer or disclose, directly or indirectly, any Product, or related technical information, document or material or direct products thereof to any individual or entity, directly or indirectly, who is (i) included on a "Restricted Parties List" maintained by the European Union, United Kingdom, United States, Ukraine or United Nations;[1] (ii) ordinarily resident, located, or organized in a jurisdiction that is the subject of country-wide or territory-wide sanctions administered by the European Union, its Member States, the United Kingdom ("UK"), Ukraine or United States, in each case, in violation of the Trade Control Laws, including but not limited to, Cuba, the Crimea region, the temporarily occupied territories of Ukraine (as this term is defined under the Ukrainian law at any time during the term of these Terms and Conditions), Iran, North Korea, or Syria; (iii) owned or controlled by, or acting on behalf of, any of the foregoing; or (iv) a party with whom transactions are otherwise prohibited under any other laws of the United States, UK, European Union or its Member States or Ukraine, unless otherwise authorized by specific or general licenses or pursuant to other authorization. Buyer covenants and agrees that it will screen or review potential customers against the Restricted Parties Lists prior to re-selling, supplying, or otherwise transferring or releasing any Products to any person. Buyer further covenants and agrees not to re-sell, supply, or otherwise transfer or release any Products in connection with these Terms and Conditions, to any person if Buyer knows or has reason to believe that such person intends to export, re-export, release, or otherwise transfer the same in violation of Trade Control Laws.

Buyer shall immediately notify BVI if Buyer has any information or suspicion that there may be a violation of the Trade Control Laws or any of the representations in this Section 9.2 in connection with Buyer's performance under these Terms and Conditions.

[1] "Restricted Party Lists" include the list of sanctioned entities maintained by the United Nations; the Specially Designated Nationals and Blocked Persons List, the Foreign Sanctions Evaders List, and the Sectoral Sanctions Identifications List, all administered by the U.S. Treasury Department; the U.S. Denied Persons List, the U.S. Entity List, and the U.S. Unverified List, all administered by the U.S. Department of Commerce; the Debarred Parties List administered by the U.S. State Department; the consolidated list of Persons, Groups and Entities of the European Union; and similar lists of restricted parties maintained by the European Union, its Member States, the United Kingdom, United States, or United Nations.

9.3 Anti-Corruption Compliance
Buyer shall take no action that violates, or would cause BVI to be in violation of, the U.S. Foreign Corrupt Practices Act (the "FCPA"), the UK Bribery Act (the "UKBA"), or similar applicable anti-bribery or anti-corruption laws. Buyer represents, warrants and covenants that it shall fully cooperate with BVI in ensuring compliance with the FCPA, UKBA and all other applicable anti-bribery or anti-corruption laws.

Buyer shall ensure that neither Buyer nor any of its principals, employees or agents shall, directly or indirectly through third parties, pay, promise or offer to pay, authorize the payment of, solicit, or accept any money or other thing of value, to or from a Public Official or Entity (as defined below) for purposes of corruptly obtaining or retaining business for or with, or directing business to, any person, including BVI, by (a) influencing any official act, decision or omission of such Public Official or Entity; (b) inducing such Public Official of Entity to do or omit to do any act in violation of the lawful duty of such Public Official or Entity; (c) securing any improper advantage; or (d) inducing such Public Official or Entity to affect or influence any act or decision of another Public Official or Entity. For the purposes of this Section, the term "Public Official" or "Entity" means (v) an officer, employee, agent or representative of any government or military; (w) any department, agency, corporate entity, instrumentality or political subdivision of any government or military; (x) any person or commercial entity acting in an official capacity for or on behalf of any government or military; (y) any candidate for political office, any foreign political party or any official of a foreign political party; or (z) any officer, employee, agent or representative of any public international organization.

Buyer shall ensure that neither Buyer nor any of its principals, employees, sub-Buyers, or agents directly or indirectly promises, offers or provides any corrupt payment, gratuity, emolument, bribe, kickback, excessive gift or hospitality or other illegal or unethical benefit to a customer, a Public Official or Entity or any other individual or organization.

Buyer shall immediately notify BVI if Buyer has any information or suspicion that there may be a violation of the FCPA, the UKBA, or any other applicable anti-bribery or anti-corruption law in connection with Buyer's performance under these Terms and Conditions.

9.4 Anti-Terrorism Compliance
Buyer represents and warrants that, in the performance of its activities and obligations under these Terms and Conditions, neither it nor any of its owners, employees, or anyone associated with it is listed in connection with any anti-terrorism law (including, without limitation, on the United States Department of Treasury Office of Foreign Assets Control's Specially Designated Nationals and Blocked Persons List) and it shall not hire or have any dealings with any person so listed, and none of its property or interests are subject to being "blocked" under any anti-terrorism law.

9.5 MDR

To the extent the Buyer assumes the role of importer or distributor of the Products in the EEA, Switzerland, the UK or part thereof, the provisions of the MDR Exhibit attached hereto shall apply.

10. Intellectual property

The trademarks, domain names, products, software, images and in general any information protected by intellectual property right (whether or not it has been registered), are and remain the exclusive property of BVI.

11. Confidentiality

During the performance of these Terms and Conditions, both parties, their directors, officers, employees and agents may have access to Information. "Information" means that information belonging to either party which is marked as confidential, or would reasonably be believed to be confidential, or which has been verbally transmitted, specifically including all details of these Terms and Conditions. Neither party's personnel shall copy, remove from the other party's facilities, disclose or use, except as specifically provided herein, any Information except solely for purposes of performing its obligations and exercising its rights under these Terms and Conditions. Upon request of the disclosing party, the party receiving such Information shall promptly return all Information and all copies thereof.

12. Applicable law and jurisdiction

All issues, questions and disputes concerning the validity, interpretation, enforcement, performance or termination of these Terms and Conditions (and any separate contract thereunder), or concerning any matters of extra-contractual and/or tort liability, if any, arising out of or in relation to these Terms and Conditions (and any separate contract thereunder), shall be governed by and construed in accordance with the internal laws of the State of Massachusetts, USA, without giving effect to any other choice-of-law or conflict-of-laws rules or provisions (whether of such the State of Massachusetts, USA or any other jurisdiction) that would cause the laws of any jurisdiction other than such country to be applicable. Parties hereby expressly exclude the United Nations Convention on Contracts for the International Sale of Goods from these Terms and Conditions and any transaction between them that may be implemented in connection with these Terms and Conditions.

Any dispute, controversy or claim arising out of or relating to these Terms and Conditions (and any separate contract thereunder), including its interpretation, validity, enforcement, performance or termination, or to a breach hereof, or concerning any matters of extra-contractual and/or tort liability, if any, arising out of or in relation to these Terms and Conditions (and any separate contract thereunder), which cannot be resolved amicably, shall be submitted to the exclusive jurisdiction of the State or federal courts of Suffolk County, Massachusetts..

13. Miscellaneous

13.1. Severability. Whenever possible, the provisions of these Terms and Conditions (and/or any separate transaction thereunder) shall be interpreted so as to be valid and enforceable under applicable law. However, if one or more provisions of these Terms and Conditions (and any separate contract hereunder) is found to be invalid, illegal or unenforceable (in whole or in part), the remainder of the provision and of these Terms and Conditions shall not be affected and shall continue in full force and effect as if the invalid, illegal or unenforceable provision(s) had never existed, subject, however, to the operation of this clause not negating the essential commercial and other aspects of these Terms and Conditions (and any separate contract thereunder).

Moreover, in this case, the parties shall amend the invalid, illegal or unenforceable provision(s) or any part thereof and/or agree on a new provision which embodies as closely as possible the purpose of the invalid, illegal or unenforceable provision(s).

13.2. Force Majeure. Neither party shall be liable if the performance of its obligations under these Terms and Conditions (and any separate contract thereunder) becomes impossible due to causes beyond its reasonable control, such as but not limited to wars, embargoes, strikes, lockouts, accidents, fires, Acts of God, pandemics, epidemics, floods or seizure, or control or rationing imposed by governmental authorities or any other occurrences beyond its reasonable control ("**Force Majeure**").

13.3. Relationship of the Parties. Nothing in these Terms and Conditions shall constitute, or be deemed to constitute a partnership between the parties nor, except as expressly provided, shall it constitute, or be deemed to constitute, any party the distributor or agent of any other party for any purpose. Subject to any express provisions to the contrary in these Terms and Conditions, Buyer shall have no right or authority to and shall not do any act, enter into any contract, make any representation, give any warranty, incur any liability, assume any obligation, whether express or implied, of any kind on behalf of BVI or bind BVI in any way. Except as expressly provided for in these Terms and Conditions, nothing in these Terms and Conditions or any separate contract thereunder shall be construed as BVI granting Buyer agency or distribution rights in respect of the sale or distribution of the Products. For the avoidance of doubt, any sale of Products as between Buyer and a third party shall be affected by Buyer as principal and not as agent or distributor of BVI and Buyer shall not hold itself out as being an agent or distributor of BVI.

13.4. Notices. Unless otherwise specified herein, all notices under these Terms and Conditions shall be in writing, and shall be effective when sent by certified mail, postage prepaid or by courier to their respective addresses. In addition, and again unless otherwise specified herein, notices shall also be effective when sent by email, if such notice is subsequently reconfirmed by certified mail, postage prepaid or by courier within 15 days of dispatch thereof by email. Each party may change its address pursuant to written notice of the other party.

MDR Exhibit

The Medical Devices Regulation (EU) 2017/45 has become fully applicable in the European Economic Area as from 26 May 2021, replacing the previous Medical Devices Directives 90/385/EEC and 93/42/EEC. The Medical Devices Regulation includes specific obligations applicable to Distributors of medical devices. Buyer shall be required to comply with the requirements of this Exhibit as from 26 May 2021 (or as from such other date on which the equivalent requirement of the MDR becomes applicable to the Product in question under the transitional provisions of Article 120 MDR).

Absent a potential agreement on the proposed modification to the Mutual Recognition Agreement (MRA) between the European Union and Switzerland, the trade facilitating effects of the MRA for medical devices falling under the new Medical Devices Regulation, including the mutual recognition of conformity assessments, the absence of the need for an Authorised Representative and the alignment of technical regulations, cease to apply as from 26 May 2021 for Switzerland.

Capitalized terms used herein shall have the meanings set forth in this Exhibit unless the context otherwise requires.

Section 1- Definitions

1.1. "Authorised Representative" shall mean any natural or legal person established within the EEA, Switzerland or the UK who has received and accepted a written mandate from a manufacturer located outside the EEA, Switzerland or the UK to act on the Manufacturer's behalf in relation to specific tasks with regard to the latter's obligations imposed by the MDR.

1.2. "Economic Operator" shall mean a Manufacturer, an Authorised Representative, an Importer, a Distributor or the natural or legal persons referred in Article 22 (1) and 22 (3) of the MDR who are responsible for placing systems or procedure packs on the EU market under their own name or who sterilizes such system or procedure packs.

1.3. "EEA" or "European Economic Area" shall mean the EU Member States and Norway, Lichtenstein and Iceland;

1.4. "Distributor" shall mean any natural or legal person in the supply chain, other than the Manufacturer or the Importer, that makes a device available on the market, up until the point of putting into service.

1.5. "Importer" shall mean any natural or legal person established within the EEA, Switzerland or the UK that places a device from a third country on the EEA market, the Swiss market or the UK market.

1.6. "Manufacturer" shall mean a natural or legal person who manufactures or fully refurbishes a device or has a device designed, manufactured or fully refurbished, and markets that device under its name or trademark. In this Exhibit, the Manufacturer shall be BVI.

1.7. "MDR" shall mean the European Medical Device Regulation (EU) 2017/745 (as amended or supplemented from time to time).

1.8. "Serious Risk" shall mean any risk or incident that directly or indirectly may lead to any of the following: (a) death of a patient, user or other person, (b) the temporary or permanent serious deterioration of a patient's user's or other person's state of health, (c) a Serious Public Health Threat.

1.9. "Serious Public Health Threat" shall mean an event which could result in imminent risks of death, serious deterioration in a person's state of health, or serious illness, that may require prompt remedial action, and that may cause significant morbidity or mortality in humans, or that is unusual or unexpected for the given place and time.

1.10. "UDI or Unique Device Identifier" shall mean a series of numeric and alphanumeric characters that is created through internationally accepted device identification and coding standards and that allows unambiguous identification of specific devices on the market.

Section 2- Regulatory obligations

2.1. Buyer shall assume the role of Importer or Distributor for the Products, as these terms are defined by Section 1.4 of this Exhibit, without prejudice to Buyer's obligations under the MDR. Buyer shall be responsible for making the Products available on the market, up until the point of putting into service. Where the Buyer acts as the Importer, the provisions of Article 2.2 - 2.6 of this Exhibit will apply. Where the Buyer acts as the Distributor, the provisions of Article 2.7 - 2.9 of this Exhibit will apply.

Importer

2.2. Buyer shall place on the market only Products that are in conformity with the MDR.

2.3 Before making the Products available on the market, Buyer shall verify that the following requirements are met:

2.3.1. The Products have been CE marked and that the EU declaration(s) of conformity for the Products have been drawn up.

2.3.2. A Manufacturer is identified and an authorised representative in accordance with Article 11 of the MDR has been designated by the Manufacturer.

2.3.3. The Products are labelled in accordance with the MDR and accompanied by the required instructions for use;

2.3.4. Where applicable, a UDI has been assigned by the Manufacturer in accordance with the MDR.

2.3.5. The Products are registered in the electronic system in accordance with Article 29 of the MDR. Buyer shall add its details to the registration in accordance with Article 31 of the MDR.

2.4. The Buyer has to indicate on the Products or on their packaging or in a document accompanying the Products its name, registered trade name or registered trade mark, its registered place of business and the address at which it can be contacted, so its location can be established. Buyer shall ensure that this additional label does not obscure any information on the label provided by the Manufacturer.

2.5. Buyer shall verify that the Products are registered in the electronic system in accordance with Article 29 of the MDR. It shall add its details to the registration in accordance with Article 31 of the MDR.

2.6. Buyer shall ensure that, while a Product is under its responsibility, storage or transport conditions do not jeopardise its compliance with the general safety and performance requirements set out in Annex I to the MDR and Buyer shall comply with the conditions set by the Manufacturer, where available.

Distributor

2.7. Before making the Products available on the market, Buyer shall verify that the following requirements are met:

2.7.1 The status of each Economic Operator for the Products has been determined and Buyer meets the definition of Distributor as provided in Section 1.4 of this Exhibit.

2.7.2 The Products have been CE marked and that the EU declaration(s) of conformity for the Products have been drawn up.

2.7.3 The Products are accompanied by the information to be supplied by the Manufacturer in accordance with the MDR (Annex I GSPR 23). This information shall be in an official language(s) determined by the states in which the Products are made available to the user or the patients.

2.7.4 For Products imported into the market, the Importer has indicated on the Products or on their packaging or in a document accompanying the Products the Importer's name, registered trade name or registered trade mark, their registered place of business and the address at which they can be contacted, so their location can be established. Buyer shall ensure that this additional label does not obscure any information on the label provided by the Manufacturer.

2.7.5 Where applicable, a UDI has been assigned by the Manufacturer in accordance with the MDR.

2.8. Buyer shall ensure that storage or transport conditions comply with the conditions set by Manufacturer while the Products are within the Buyer's responsibility.

Transitional arrangements

2.9. Buyer shall make devices which were lawfully placed on the market in accordance with Directives 90/385/EEC and 93/42/EEC available on the market or put into service by complying to the relevant requirements of Article 120 of the EU MDR.

Devices lawfully placed on the market pursuant to Directives 90/385/EEC and 93/42/EEC prior to 26 May 2020, and devices placed on the market from 26 May 2020 by virtue of a certificate as explained later in this section, may continue to be made available on the market or put into service until 27 May 2025.

Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC prior to 25 May 2017 shall remain valid until the end of the period indicated on the certificate, except for certificates issued in accordance with Annex 4 to Directive 90/385/EEC or Annex IV to Directive 93/42/EEC which shall become void at the latest on 27 May 2022. Certificates issued by notified bodies in accordance with Directives 90/385/EEC and 93/42/EEC from 25 May 2017 shall remain valid until the end of the period indicated on the certificate, which shall not exceed five years from its issuance. They shall however become void at the latest on 27 May 2024.

Buyer shall agree with BVI about the last possibility to place devices on the market. Also, Buyer shall establish a system to differ between devices lawfully placed on the market in accordance with Directives 90/385/EEC and 93/42/EEC and devices lawfully placed on the market in accordance with the EU MDR 2017/745. Devices placed on the market in accordance with the Directives, cannot be made available on the market or put into service after 27 May 2025.

Section 3- Complaints and other reports from healthcare professionals, patients or users

3.1. If the Buyer receives complaints or reports from healthcare professionals, patients or users regarding suspected incidents related to the Products that Buyer has made available, the Buyer shall immediately forward this information to Manufacturer at the email address set out in Section 9 of this MDR Exhibit and, where applicable, its Authorized Representative and the Importer.

3.2. The Buyer shall not perform any investigation which involves altering the device or a sample of the batch concerned in a way which may affect any subsequent evaluation of the causes of the incident.

3.3. Buyer shall keep a register of complaints, of non-conforming Products and of recalls and withdrawals, and keep Manufacturer and, where applicable, the Authorised Representative, the Importer and the Distributors informed of such monitoring and provide them with any information upon their request.

Section 4- Non-compliance with the MDR

4.1. Products not yet made available in the market by the Buyer. If the Buyer considers or has a reason to believe that the Products are not in conformity with the requirements of the MDR, the Buyer shall not make the Products available on the market until they have been brought in conformity with these requirements. The Buyer shall also inform Manufacturer at the email address set out in Section 9 of this MDR Exhibit, and where applicable Manufacturer's Authorised Representative, of this non-conformity. Where the Buyer considers or has reason to believe that the Products present a Serious Risk or are falsified Products, Buyer shall also inform the competent authority of the state in which the Buyer is established.

4.2 Products already made available on the market. If the Buyer considers or has reason to believe that Products which the Buyer has made available on the market are not in conformity with the MDR, the Buyer shall immediately inform the Manufacturer at the email address set out in Section 9 of this MDR Exhibit, and where applicable Manufacturer's Authorised Representative. Buyer shall cooperate with Manufacturer, and where applicable Manufacturer's Authorised Representative and Importer, and with the competent authorities of the relevant states to ensure that the necessity corrective action to bring that Products into conformity, and to withdraw or recall the Products, if appropriate, is taken.

Importer
Where the Products present a Serious Risk, the Buyer, when acting as an Importer, shall act in accordance with any reasonable instructions given by the Manufacturer, without prejudice to its obligations to also immediately inform the competent authorities of the states in which it made the Products available and, if applicable, the notified body that issued a certificate in accordance with Article 56 of the MDR for the Product in question, giving details, in particular, of the non-compliance and of any corrective action taken.

Distributor
Where the Buyer, when acting as a Distributor, considers or has reason to believe that the Products present a Serious Risk, the Buyer shall immediately act in accordance with any reasonable instructions given by the Manufacturer, without prejudice to its obligations to also immediately inform the competent authorities of the states in which the Buyer made the Products available, giving details in particular, of the non-compliance and of any corrective action taken.

Section 5- Regulatory Compliance
5.1. In application of Art. 30 of MDR (EU) 2017/745, the Buyer shall follow, if applicable, national provisions on registration of distributors as defined by the relevant state that may be maintained or introduced. The Buyer shall inform the Manufacturer about such provisions.

Section 6- Cooperation with competent authorities
6.1 Buyer, where acting as the Importer, shall cooperate with competent authorities, at the latters' request, on any action taken to eliminate or, if that is not possible, mitigate the risks posed by the devices. Where the Buyer acts as a Distributor, Buyer 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.

6.2. Buyer shall immediately notify the Manufacturer if Buyer receives a request from a competent authority to provide information and/or documentation about Products' compliance or receives a request or order to cooperate with competent authorities, at their request, on any action to be taken to eliminate the risks posed by the Products. Buyer shall immediately provide Manufacturer with copies of all documents provided to or received from any competent authority and a written summary of any discussion undertaken with such authority. Distributor shall inform the Manufacturer immediately of any follow up requests from the competent authorities.

6.3. If Buyer receives a request or order to cooperate with competent authorities to provide free samples of the Products or grant access to the Products, Buyer shall immediately inform Manufacturer and provide free samples to the competent authority or, where that is impracticable, grant access to the Products. If the competent authorities request or order access to the Products, Buyer shall, if reasonably practicable, enable Manufacturer to have a representative present at the location of the Products at the time of access by the competent authorities.

Section 7- Retention of Records / Traceability
7.1. Buyer shall cooperate with the Manufacturer and the Authorised Representative to achieve and maintain an appropriate level of traceability for the Products. For this purpose, the Buyer shall keep detailed record in relation to the sourcing and supply of the Products for a period of at least 10 (or for PhysIOL Products: 35) years after the last Products covered by the declaration of conformity have been placed on the market. In case of implantable devices, the period shall be at least 15 (or for PhysIOL Products: 35) years after the last Products have been placed on the market. These records, which shall be provided to the competent authorities of the relevant states upon request, shall include appropriate information to identify:

7.1.1. Customers or Economic Operators to whom Buyer has directly supplied the Products;
7.1.2. Suppliers or Economic Operators who have directly supplied Products to the Buyer;
7.1.3. Any health institution or healthcare professional to which/to whom the Buyer has directly supplied Products

7.2. In addition and in application of Art. 27.8 of the MDR (EU) 2017/745, the Buyer shall store and keep, preferably by electronic means, the UDI of class III implantable devices which Buyer has supplied or with which Buyer has been supplied and any other type of device to which that Article applies.

7.3. These documents must be retained in a manner that ensures that they are protected against damage from the elements and theft. At the end of the retention period, Buyer shall notify Manufacturer in writing, requesting that arrangements be made for picking up the documents from Buyer or Manufacturer's agreement to their destruction. In the event of termination of the business relationship between Manufacturer and Buyer, Buyer shall, unless otherwise agreed in writing, retain the above documents until the end of the retention period. In the event of the Buyer's liquidation or insolvency, the documents shall be delivered to Manufacturer without prompting or without additional costs.

7.4. Buyer, when acting as an Importer, shall 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 of the MDR, for a period of at least 10 years after the last Products covered by such declaration of conformity or relevant certificate have been placed on the market. In case of implantable devices, the period shall be at least 15 years after the last Products have been placed on the market.

Section 8 - Consequences as of 26 May 2021 for Switzerland

Access for Swiss Manufacturers to the EU/EEA market

8.1. Swiss Manufacturers intending to place their devices on the EU/EEA market must establish an Authorized Representative in the EU/EEA.

8.2. New Swiss medium- and high-risk devices of Swiss Manufacturers must be certified by conformity assessment bodies established within the EU/EEA.

8.3. Existing certificates issued under the MRA by conformity assessment bodies established in Switzerland will no longer be recognized as valid in the EU/EEA. It must be ensured that devices are certified by an EU/EEA conformity assessment body where such certification is required on the basis of the applicable conformity assessment procedure.

8.4. Existing certificates issued under the MRA by notified bodies established in the EU/EEA will be recognised by the EU/EEA, provided that the Swiss Manufacturer has designated an Authorized Representative in the EU/EEA.

Access for EU/EEA Manufacturers/Distributors to the Swiss market

8.5. On 19 May 2021, the Swiss Federal Council adopted an amendment to the Swiss Ordinance on Medical Devices (MDO), which has also become fully applicable on 26 May 2021, establishing conditions for the trade of medical devices by EU/EEA Manufacturers/Distributors on the Swiss market. This includes the recognition of existing certificates issued under the MRA by conformity assessment bodies established in the EU/EEA and transitional timelines for the designation of an Authorized Representative in Switzerland for EU/EEA Manufacturers/Distributors of medical devices.

8.6. Manufacturers/Distributors established in the EU/EEA intending to place devices on the Swiss market must designate an Authorized Representative for all devices placed on the Swiss market after 26 May 2021 within the following deadlines:

a. for class III devices, class IIb implantable devices, and active implantable medical devices: until 31 December 2021;

b. for class IIb non-implantable devices and class IIa devices: until 31 March 2022;

c. for class I devices, systems and procedure packs: until 31 July 2022.

and must ensure that the labelling of the devices is adjusted by the time the new Authorized Representative is designated.

8.7. Certificates issued by notified bodies established in the EU/EEA will be treated by Switzerland as certificates issued by Swiss notified bodies if it can be credibly shown that (i) the conformity assessment procedures applied meet the Swiss requirements, and (ii) they are issued by a body with qualifications equivalent to those required in Switzerland.

8.8. For devices already placed on the Swiss market prior to 26 May 2021, the required information must be registered with Swissmedic by 26 November 2021.

8.9. For devices placed on the Swiss market after 26 May 2021, the required information must be registered with Swissmedic within three months of placing a device on the Swiss market for the first time.

8.10. Manufacturers/Distributors established in the EU/EEA must make any other registration and notification as required, such as notification of the Unique Device Identifier (UDI), serious incidents in connection with the device concerned or field safety corrective measures taken in Switzerland, to Swissmedic.

8.11. Manufacturers/Distributors established in the EU/EEA must provide access to the technical documentation either by keeping a copy available at the Swiss Authorised Representative or by contractually guaranteeing that it will be handed over to Swissmedic upon request within 7 days.

8.12. Manufacturers/Distributors established in the EU/EEA must publish the validated Summary of Safety and Clinical Performance (SSCP), for example on their website (only applicable to implantable devices).

Section 9 - Notices

Notwithstanding Section 13.4 of the Terms and Conditions, all notices in relation to complaints and non-conformities as set out under Sections 3.1, 4.1 and 4.2 of this MDR Exhibit are to be sent by simple email to:

- For ARCAD Products: mmillan@bvimedical.com
- For BVI and Vitreq Products: CKotsopulos@bvimedical.com
- For Optikon Products: rrowe@bvimedical.com
- For PhysIOL Products: complaints@physiol.be