

**The Terms & Conditions between ORGANON and Supplier: (VERSION 15, April 12, 2021)**

The original of "**ORGANON K.K. STANDARD TERMS & CONDITIONS PURCHASE OF**

**GOODS AND SERVICES**" shall be the one in the Japanese language, which shall prevail in all events, and any version thereof in any other language, including but not limited to the English language, shall be deemed to be a translation, which shall have no legal effect whatsoever.

- "**ORGANON K.K. STANDARD TERMS & CONDITIONS PURCHASE OF GOODS AND SERVICES**", published as of the day when the transaction described on this Purchase Order is made, shall apply to such transaction between ORGANON K.K. or its affiliates (ORGANON K.K. and its affiliates collectively, "ORGANON") and the seller or the contractor as the case may be ("Supplier"), unless ORGANON and Supplier have made a certain agreement.
- If an affiliated company of ORGANON K.K. is an ordering party of the transaction described on this Purchase Order, the term "ORGANON" and "ORGANON K.K." referred in **ORGANON K.K. STANDARD TERMS & CONDITIONS PURCHASE OF GOODS AND SERVICES** shall be deemed to be replaced with the company name of such affiliated company.
- Please check "**ORGANON K.K. STANDARD TERMS & CONDITIONS PURCHASE OF GOODS**" and "**ORGANON K.K. STANDARD TERMS & CONDITIONS PURCHASE OF SERVICES**" by referring to the following:

**ORGANON K.K. STANDARD TERMS & CONDITIONS  
PURCHASE OF GOODS (VERSION 15, April 12, 2021)**

The Terms & Conditions set forth below shall apply to each sale and purchase agreement by and between ORGANON K.K. as a purchaser (hereinafter referred to as “ORGANON”), and the other party thereto as a seller (hereinafter referred to as “Supplier”) concerning any product (hereinafter referred to as the “Product”) to be sold by Supplier to ORGANON and purchased by ORGANON from Supplier.

**ARTICLE 1 FORMATION OF THE SALE AND PURCHASE AGREEMENT**

- 1.1 A sale and purchase agreement (hereinafter referred to as the “Individual Agreement”) by and between Supplier and ORGANON concerning the Product shall become effective (i) upon Supplier’s issuance to ORGANON of written notice of Supplier’s acceptance of ORGANON’s written purchase order in ORGANON’s prescribed form, which sets forth the Product’s name, specifications, standards, quantity, order date, delivery due date, delivery location, unit price, transaction price, payment due date and other specific information necessary for the sale and purchase; or (ii) as of the date which is three (3) business days after the date on which Supplier receives the written purchase order, if Supplier fails to issue written notice of rejection of the written purchase order within such three (3) business day period. These Terms & Conditions and the provisions set forth in the applicable written purchase order shall constitute the provisions of the Individual Agreement. If ORGANON’s written purchase order notes the date on which ORGANON wishes to have the Products delivered, such date shall be deemed to mean, in principle, the Product’s delivery due date.
- 1.2 If, after ORGANON’s issuance to Supplier of a written purchase order described in the preceding Paragraph, Supplier provides ORGANON with notice of other terms and conditions (hereinafter referred to as “Supplier’s Terms & Conditions”), which are either different from these Terms & Conditions or which include additional terms and conditions, no Individual Agreement shall become effective, except when ORGANON provides Supplier with written notice of ORGANON’s acceptance of Supplier’s Terms & Conditions.
- 1.3 Notwithstanding the provisions of the preceding Paragraph, if Supplier delivers the Product to ORGANON prior to ORGANON’s issuance to Supplier of written notice of ORGANON’s acceptance of Supplier’s Terms & Conditions, Supplier’s Terms & Conditions shall be null and void, and these Terms & Conditions and the provisions set forth in the applicable written purchase order shall constitute the provisions of the Individual Agreement.
- 1.4 The Product’s unit price and transaction price to be set forth in ORGANON’s written

purchase order shall be determined through consultation by and between ORGANON and Supplier based on the written estimates submitted by Supplier to ORGANON; provided, however, that, in the event that the Product's unit price or transaction price has previously been separately agreed upon by and between ORGANON and Supplier, ORGANON shall set forth in its written purchase order the unit price or transaction price which conforms to such agreement.

- 1.5 The Product's transaction price to be set forth in ORGANON's written purchase order shall be the price as delivered to the designated delivery location, which includes the packaging, transportation and all other expenses (net of consumption taxes); provided, however, that, if ORGANON's written purchase order sets forth price-related terms that are different from the foregoing, such terms shall prevail.
- 1.6 The provisions of an Individual Agreement may be amended upon prior consultation by and between ORGANON and Supplier; the procedures for making such amendments shall be the same as those procedures described in Paragraph 1.1 above.

## **ARTICLE 2 DELIVERY**

- 2.1 Supplier shall, in compliance with the provisions of the Individual Agreement, deliver the Product, together with a delivery notice and other necessary documents in the form prescribed by ORGANON, on or before the delivery due date. If ORGANON wishes to change the delivery due date or other delivery conditions for its convenience, ORGANON shall hold prior consultations with Supplier, and Supplier shall cooperate with ORGANON.
- 2.2 Supplier shall comply with instructions, if any, issued by ORGANON concerning the method of packaging and transporting the Product, etc.
- 2.3 If, in connection with the delivery of the Product, preparations for accepting heavy, hazardous, etc., products are deemed to be required, Supplier shall deliver prior notice to the address designated by ORGANON setting forth the delivery date/time and special handling instructions.
- 2.4 Immediately upon the occurrence of any event which prevents, or may prevent, Supplier from delivering the Product in whole or in part on or before the delivery due date, Supplier shall notify ORGANON of the reason therefor, the estimated delivery date, etc., and comply with ORGANON's instructions. If the Product is not delivered on or before the delivery due date due to a cause for which Supplier should be held responsible, ORGANON shall have the right to demand that Supplier pay compensation for damages suffered by ORGANON as a result thereof.
- 2.5 Supplier shall obtain ORGANON's prior consent, if Supplier wishes to deliver the Product prior to the delivery due date.

## **ARTICLE 3 SAFETY, DISASTER PREVENTION AND ENVIRONMENTAL**

### **PROTECTION MEASURES TO BE TAKEN AT THE TIME OF DELIVERY**

- 3.1 Supplier shall deliver the Product in compliance with the applicable laws, ordinances and regulations, as well as various rules and instructions prescribed or issued by ORGANON, taking into consideration issues relating to safety, disaster prevention and environmental protection.
- 3.2 Whenever Supplier causes a third party designated by Supplier to deliver the Product, Supplier shall cause such party to comply with Supplier's obligations set forth in the preceding Paragraph.
- 3.3 Supplier shall immediately notify ORGANON upon the occurrence of any loss, accident or environmental pollution which affects ORGANON, Supplier or any third party arising from the delivery of the Product.
- 3.4 If the loss, accident or environmental pollution referenced in the preceding Paragraph occurs due to a cause for which Supplier should be held responsible, Supplier shall, at Supplier's cost and as Supplier's responsibility, urgently take appropriate remedial measures. In addition, Supplier shall pay compensation for damages suffered by ORGANON or any third party as a result of such loss, accident or environmental pollution.

### **ARTICLE 4 ACCEPTANCE INSPECTION**

- 4.1 ORGANON shall, immediately after its receipt of the delivered Product, confirm the quantity and packaging condition. If deemed necessary by ORGANON or Supplier, an acceptance inspection shall be conducted in accordance with the inspection method and inspection standards previously prescribed by ORGANON and Supplier through mutual consultation, and ORGANON shall notify Supplier of the results thereof without delay.
- 4.2 If ORGANON discovers anything not conforming to the terms of this Agreement or any Individual Agreement regarding the quality or quantity of the Product (the "**Non-Conforming Item**") as a result of the confirmation of the quantity or packaging condition referenced in the preceding Paragraph or the acceptance inspection referenced in the preceding Paragraph, Supplier shall deliver the missing or replacement Product, repair the Product containing Non-Conforming Item (the "**Substandard Product**"), or take other measures in compliance with ORGANON's instructions within the period separately specified by ORGANON, and ORGANON shall inspect or re-inspect the Product so delivered or repaired.
- 4.3 In the event, despite ORGANON's instructions referenced in the preceding Paragraph, Supplier fails to deliver the missing or replacement Product or repair the Substandard Product within the period specified by ORGANON, or in the event that the reason for the Substandard Product is based on a minor defect and it is recognized that the

Substandard Product can be used through ORGANON innovations, ORGANON may specially adopt and receive the Substandard Product as a special exception limited to this Substandard Product, conditionally upon the reduction of the purchase price amount in accordance with the degree of the non-conformity.

- 4.4 If ORGANON requests that Supplier retrieve the Substandard Product, Supplier shall retrieve the Substandard Product within the period separately prescribed by ORGANON; during such period, ORGANON shall keep custody of the Substandard Product with the care of a good manager.
- 4.5 Upon the expiration of the period referenced in the preceding Paragraph, ORGANON shall have the right to return the Substandard Product to Supplier, or dispose of the Substandard Product with Supplier's consent. In such event, Supplier shall pay the cost and expenses incurred in connection with such return or disposal.
- 4.6 Nothing in this Article shall prejudice ORGANON's right to claim damage compensations from Supplier.

## **ARTICLE 5 TRANSFER OF OWNERSHIP**

Ownership of the Product shall be transferred from Supplier to ORGANON (i) upon the completion of ORGANON's confirmation of the quantity and packaging condition, if no acceptance inspection is conducted by ORGANON; and (ii) if an acceptance inspection is conducted, when the Product passes the acceptance inspection or when a decision is made to accept the Product on a limited and exceptional basis.

## **ARTICLE 6 RISK OF LOSS, ETC.**

(i) Until ownership is transferred pursuant to the provisions of the preceding Article, Supplier shall bear the risk of loss of or damage to the Product due to any reason not attributable to neither of the parties hereto, including but not limited to force majeure and other unavoidable events, and ORGANON may, at its option, refuse to pay the purchase price for such Product or terminate the Individual Agreement in relation to such Product; and (ii) after such transfer of ownership, ORGANON shall bear such risk and shall not be entitled to demand the delivery of the replacement or the repair of the Product by reason of the loss or damage. Notwithstanding the foregoing, after the Product is delivered and before the ownership is transferred, ORGANON shall keep custody of the Product with the care of a good manager.

## **ARTICLE 7 PAYMENT**

- 7.1 Supplier shall submit to ORGANON an accurately prepared invoice after the Product is delivered.
- 7.2 ORGANON shall pay the purchase price of the Product, whose ownership has been transferred to ORGANON, within 90 days, after the receipt of the invoice referenced

in the preceding Paragraph, by making a remittance to an account at a financial institution designated by Supplier. Notwithstanding the foregoing, if ORGANON's written purchase order sets forth payment terms which are different from the foregoing, ORGANON's payment shall be made in accordance with such payment terms set forth in ORGANON's written purchase order.

- 7.3 If any payment pursuant to this Agreement is made by way of by making a remittance to an account at a financial institution, such payment shall be deemed to become effective upon the payer having completed a remittance request at the remitting bank.
- 7.4 Upon submitting an invoice, Supplier shall attach a document with a valid issue date pursuant to the expense policy set forth separately by ORGANON. In case ORGANON requests, Supplier also shall provide ORGANON with evidentiary materials (invoices issued by its subcontractor etc.) to show the cost paid to the subcontractor is reasonable. If Supplier does not comply with the above, ORGANON has a right to withhold payments to a reasonable extent.

## **ARTICLE 8 QUALITY ASSURANCE, DATA INTEGRITY**

- 8.1 Supplier warrants that the Product's quality shall be such that it will comply with the specifications designated by ORGANON, as well as the laws, regulations and safety standards applicable to the Product.
- 8.2 Supplier shall create the quality management standards and methods of inspection, etc. for the Product to warrant the quality of the Product, and thereby carry out the quality management and inspection, etc. in a responsible manner.
- 8.3 Supplier endeavors to establish the quality management system and carries out an adequate quality management in the case of the Product newly designed, the alteration of the design, or the alteration of the process.
- 8.4 ORGANON may, when it finds it necessary to do so, request Supplier to provide the document which warrants the quality of the Product.
- 8.5 Supplier shall keep the drawing, specification and plan of the quality of the Product, technical information materials of the manufacturing, the guideline and result of the examination or inspection, and the respective originals of the rules (including anything equivalent to the originals), etc. pursuant to the document keeping standards, and respond promptly if ORGANON requests Supplier to submit these documents.
- 8.6 Any documentation or data relevant to activities performed, including without limitation any GMP documentation, must be attributable, original, accurate, legible, complete, controlled, retrievable, and safe from intentional or unintentional manipulation or loss. These items are required throughout the retention period of such data / documentation.

## **ARTICLE 9 LIABILITY FOR NON-CONFIRMING ITEM**

- 9.1 If ORGANON discovers Non-Conforming Item not discovered in the inspection under Article 4, Paragraph 1 that has not arisen due to any reason attributable to ORGANON,

ORGANON may, within one (1) year from the time ORGANON becomes aware of such Non-Confirming Item, request Supplier to deliver the replacement Product, repair the Non-Confirming Item, or reduce the purchase price amount (or refund the payment price).

- 9.2 Nothing in the preceding Paragraph shall prejudice ORGANON's right to claim damage compensations from Supplier.
- 9.3 Even after the expiration of the period referenced in the Paragraph 1, Supplier shall pay compensation for damages suffered by ORGANON due to a material Non-Confirming Item for which Supplier should be held responsible.

#### **ARTICLE 10 CONFIDENTIALITY OBLIGATION**

- 10.1 Supplier shall not disclose or divulge to any third party the fact that the Individual Agreement has been entered into, any of the terms and conditions of the Individual Agreement, or information concerning ORGANON disclosed or obtained in connection with the performance of the Individual Agreement (hereinafter collectively referred to as the "Confidential Information").
- 10.2 Supplier shall not use the Confidential Information for any purpose other than its performance of the Individual Agreement.
- 10.3 Notwithstanding the provisions of the preceding two (2) Paragraphs, Supplier's obligations under the preceding two (2) Paragraphs shall not apply to any information which can be proved to constitute information described in one of the following Items:
- ① Information which was already in Supplier's possession when it is disclosed by or obtained from ORGANON;
  - ② Information which was already publicly known or used when it is disclosed by or obtained from ORGANON;
  - ③ Information which becomes publicly known or used, due to causes for which Supplier should not be held responsible, after it is disclosed by or obtained from ORGANON;
  - ④ Information which is legally obtained by Supplier without any confidentiality obligation from a third party which has the proper right to make the disclosure to Supplier; or
  - ⑤ Information which is independently developed by Supplier, after Confidential Information is disclosed by or obtained from ORGANON, without any relation to the disclosed Confidential Information.

#### **ARTICLE 11 COMPENSATION FOR DAMAGES**

If, in connection with the performance of the Individual Agreement, ORGANON suffers damages due to causes for which Supplier should be held responsible, Supplier shall pay ORGANON compensation for such damages.



## ARTICLE 12 PRODUCT LIABILITY

- 12.1 If any incident occurs due to a defect (i.e., any “defect” as such term is defined in Article 2, Paragraph 2, of the Product Liability Law of Japan; the same shall apply hereinafter) in the Product, ORGANON and Supplier shall cooperate with each other in order to investigate its cause.
- 12.2 Supplier shall notify ORGANON immediately and endeavor to minimize damages if (i) Supplier receives notice that the Product is actually, or may potentially be, defective; or (ii) Supplier receives from a third party a claim for compensation for damages arising from any defect in the Product.
- 12.3 If ORGANON suffers any loss arising from any defect in the Product, due to damages caused by the Product or any product incorporating the Product and suffered by ORGANON or any third party (including situations where ORGANON pays damage compensation to such third party), Supplier shall pay ORGANON compensation for damages which have reasonable causation (*soutou inga kankei*) with the defect (including attorneys’ fees, investigation expenses, etc.); provided, however, that the foregoing shall not apply in the event described in either of the following Items:
- ① The defect in the Product could not be identified by the scientific technologies which existed when the Product was delivered; or
  - ② The defect arose solely from Supplier’s compliance with ORGANON’s instructions, and Supplier did not commit any negligence that contributed to the existence of the defect.
- 12.4 Supplier shall, upon mutual consultation with ORGANON, obtain, at Supplier’s cost, general liability insurance in an amount which is sufficient to cover the obligation to pay third parties compensation for damages arising from the use or sale of the Product.

## ARTICLE 13 INFRINGEMENT ON THIRD PARTIES’ RIGHTS

- 13.1 Supplier warrants that neither the Product, nor its manufacturing method, infringes on any third party’s patent right, utility model right, design right, trademark right or any other industrial property right, copyright or any other intellectual property right (hereinafter collectively referred to as the “Intellectual Property Right, Etc.”). Supplier shall provide ORGANON with immediate notice if any dispute arises or may arise in connection with any third party’s Intellectual Property Right, Etc., resolve such dispute at Supplier’s cost and as Supplier’s responsibility, and hold ORGANON harmless from any and all damages whatsoever.
- 13.2 Supplier warrants that neither the Product, nor its manufacturing method, utilizes any third party’s trade secret. Supplier shall provide ORGANON with immediate notice if any dispute arises or may arise in connection with any third party’s trade secret, resolve such dispute at Supplier’s cost and as Supplier’s responsibility, and hold ORGANON



harmless from any and all damages whatsoever.

- 13.3 ORGANON shall provide Supplier with immediate notice if ORGANON receives any claim from a third party, or if a lawsuit is brought against ORGANON by a third party, concerning the Product's infringement on such third party's Intellectual Property Right, Etc., or the Product's use of such third party's trade secret, and Supplier shall resolve such dispute at Supplier's cost and as Supplier's responsibility. ORGANON shall cooperate with Supplier to resolve such dispute upon Supplier's request in connection with the resolution of such dispute.

#### **ARTICLE 14 ASSIGNMENT OF RIGHTS AND OBLIGATIONS**

Neither ORGANON, nor Supplier, shall assign, or create security interest on, all or a part of its rights, or delegate all or a part of its obligations, under the Individual Agreement, without the other party's prior written consent; provided, however, that no assignment of any right under this Agreement or the Individual Agreement constitutes a breach of this Article if the party who intends such assignment (i) notifies the assignee of the existence and contents of the restrictions as set out in this Article in advance of such assignment in writing and (ii) delivers to the other party a certified copy of the written notice.

#### **ARTICLE 15 COMPLIANCE, ETHICS, AND CONFLICT OF INTEREST**

- 15.1 Supplier agrees that in its performance under the Individual Agreement, it shall adhere to all applicable laws, regulation, ordinances and guidance, business practices that are in accordance with the spirit of such applicable laws and ethical principles, and following provisions:
- ① Supplier agrees that all transactions in connection with the Individual Agreement will be accurately reflected in its books and records, and that no funds or other assets shall be paid directly or indirectly to government officials or persons acting on their behalf for the purpose of influencing government decisions or actions with respect to ORGANON's business; and
  - ② Supplier further agrees to conduct its activities under the Individual Agreement and its dealings with ORGANON, subcontractors, and third parties so as to avoid loss or embarrassment to ORGANON due to any real or apparent conflict of interest, and to require that all subcontractors comply with such policy in connection with the Individual Agreement.
- 15.2 ORGANON shall have the right to terminate the Individual Agreement upon violation of business practices referenced in the preceding Paragraph on the part of the Supplier, its employees, agents, representatives, subcontractors, consultants, or temporary contractors.

## **ARTICLE 16 ORGANON'S BUSINESS PARTNER CODE OF CONDUCT**

1. ORGANON endeavors to hold itself and its Supplier to the highest ethical and compliance standards, including basic human rights, encouraging fair and equal treatment for all persons, the provision of safe and healthy working conditions, respect for the environment, the adoption of appropriate management systems and the conduct of business in an ethical manner. Without limiting any of Supplier's other obligations hereunder, and without conflicting with or limiting any of the warranties, obligations or other provisions expressly set forth elsewhere in the Individual Agreement, including without limitation its obligations under Article 3.1 hereof, Supplier agrees that it will abide by the letter and spirit of ORGANON's Business Partner Code of Conduct (the "Code"), as in effect from time to time, a copy of which is available at [https://www.organon.com/wp-content/uploads/sites/2/2021/05/Business-Partner-Code-Of-Conduct\\_v1.pdf](https://www.organon.com/wp-content/uploads/sites/2/2021/05/Business-Partner-Code-Of-Conduct_v1.pdf)
- 16.1 Supplier agrees that it will provide all documentation reasonably requested by ORGANON to demonstrate compliance with the Code. In the event of a conflict between the obligations in this Article 16.1 and the Code, on the one hand, and any other provision in the Individual Agreement, on the other hand, such other provision of the Individual Agreement shall control (but only to the extent of the conflict).
- 16.2 ORGANON reserves the right, in its sole discretion, to audit Supplier's operations, books and records to ensure compliance with the Code. ORGANON will provide reasonable advance notice of such an audit, and may conduct this audit on its own or using a third-party auditor of its choosing. Supplier shall acknowledge receipt of ORGANON's notice as promptly as practicable after receipt of such notice and will confirm the date on which the audit will occur within fourteen (14) days after receipt of such notice. ORGANON or its third-party auditor may interview Supplier's employees as part of or in connection with the audit. This audit right shall be in addition to any other audit rights granted in the Individual Agreement.
- 16.3 In the event an audit identifies a non-conformance by Supplier with the Code, Supplier will promptly take corrective action to remedy the non-conformance. ORGANON reserves the right to approve all corrective actions. Corrective actions shall be implemented by Supplier at Supplier's expense. ORGANON will endeavor, whenever practicable, to work with Supplier to remedy the issue and put in place a corrective action plan.
- 16.4 In the event Supplier refuses to allow an audit, or fails or refuses to take corrective action, then in addition to any other remedy available to it under the Individual Agreement, at law or in equity, ORGANON reserves the right to terminate the Individual Agreement in the event Supplier fails to cure such refusal or failure within ninety (90) days after written notice from ORGANON.

## **ARTICLE 17 SUPPLIER EXPECTATIONS**

Without limiting any of Supplier's other obligations hereunder and without limiting

any of the express warranties or obligations agreed to elsewhere in the Individual Agreement, including without limitation its obligations under Article 3.1 hereof, ORGANON expects that Supplier will abide by the letter and spirit of ORGANON's Supplier Performance Expectations, as in effect from time to time, a copy of which is available at <https://www.organon.com/wp-content/uploads/sites/2/2021/04/Organon-Supplier-Performance-Expectations.pdf> In the event of a conflict between the obligations in this Article and ORGANON's Supplier Performance Expectations, on the one hand, and any other provision in the Individual Agreement, on the other hand, such other provision of the Individual Agreement shall control (but only to the extent of the conflict).

## **ARTICLE 18 EXCLUDED ENTITIES**

18.1 The term "Violation" as used in this Article shall mean that either Supplier, or any of its officers or directors has been (each of (1), (2) and (3) collectively the "Exclusions Lists"):

- (1) convicted of any of the felonies identified among the exclusion authorities listed on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) website (<http://exclusions.oig.hhs.gov/>), including 42 U.S.C. 1320a-7(a);
- (2) identified in the OIG List of Excluded Individuals/Entities (LEIE) database (<http://oig.hhs.gov/fraud/exclusions.asp>) or the U.S. General Services Administration's list of Parties Excluded from Federal Programs (<https://www.sam.gov/SAM/>); or
- (3) listed by any US Federal agency as being suspended, debarred, excluded, or otherwise ineligible to participate in Federal procurement or non-procurement programs.

18.2 Supplier represents and warrants that prior to the date of this Agreement, it has screened itself, and its officers and directors against the Exclusions Lists and that it has informed ORGANON whether it, or any of its officers or directors has been in Violation. After the execution of this Agreement, Supplier shall notify ORGANON in writing immediately if any such Violation occurs or comes to its attention. ORGANON shall also have the right, in its sole discretion, to terminate the Individual Agreement as well as other agreements then effective between ORGANON and Supplier if any, immediately in the event of any such Violation.

## **ARTICLE 19 SELF-CERTIFICATION DENIED PARTIES CLAUSES**

19.1 Supplier represents and warrants that it is not nor any of its legal representatives, as applicable, are listed on any of the U.S. or EU denied parties lists, or any other denied

parties list issued by another jurisdiction which is applicable to the products or technical data supplied under the Agreement, as notified by ORGANON to it from time to time, all of the foregoing collectively referred to as “Denied Parties Lists”. As of the date of this Memorandum, the Denied Parties Lists consist of the U.S. Treasury Department (<https://home.treasury.gov/>)’s List of Specially Designated Nationals and Blocked Persons (the “SDN List”), the U.S. Commerce Department (<https://www.bis.doc.gov/>)’s Denied Persons List and Entity List, and the Consolidated List of Persons, Groups and Entities Subject to EU Financial Sanctions (<https://ec.europa.eu/>). Supplier further represents and warrants that it is not directly owned by 50% or more by a person or an entity listed on the SDN List. Supplier further represents and warrants that it shall notify ORGANON in writing immediately if it or any of its legal representatives become listed on any of the U.S. or EU denied parties lists or if it becomes owned by 50% or more by a person or an entity listed on the SDN List.

- 19.2 In case of an inaccuracy in or a breach of the representations and warranties provided in the preceding paragraph, ORGANON has the right, in its sole discretion, to terminate the Agreement immediately and without penalty to ORGANON. Supplier agrees to indemnify and hold harmless ORGANON for any inaccuracy or breach of the representations and warranties provided in the preceding paragraph.
- 19.3 This Article shall survive termination or cancellation of the Agreement.

## **ARTICLE 20 PUBLICITY**

Supplier agrees not to advertise or otherwise make known to others any information regarding the terms and conditions, or existence of the Individual Agreement. Supplier further agrees not to use or reference in any advertising, sales promotion, press release or other communication, any company or representative name, endorsement, direct or indirect quote, code, drawing, logo, trademark, specification, or picture of ORGANON (ORGANON K.K., and its affiliates ((i) any corporation or business entity of which fifty percent (50%) or more is owned directly or indirectly by ORGANON K.K.; or (ii) any corporation, or business entity that owns directly or indirectly fifty percent (50%) or more of ORGANON K.K., or (iii) any corporation, or business entity under the direct or indirect control of any party described in (i) or (ii))) without the prior written consent of ORGANON.

## **ARTICLE 21 AUDIT RIGHTS**

- 21.1. Supplier’s records, which shall include, but not be limited to, accounting records, time sheets, written policies and procedures, test results, reports, correspondence, memoranda and any other documentation relating to the performance of the

Individual Agreement, shall be open to inspection and subject to audit and/or reproduction, during normal working hours, by ORGANON or its authorized representative to the extent necessary to adequately evaluate claims submitted by Supplier, as required by governmental authorities or as desirable for any other valid business purpose. For the purpose of such audits, inspections, examinations and evaluations, ORGANON or its authorized representative shall have access to the foregoing records beginning on the effective date and continuing until seven (7) years after the satisfaction of Supplier's obligations under the Individual Agreement. In addition, Supplier shall provide adequate and appropriate workspace for ORGANON or its authorized representatives to conduct such audit. ORGANON or its authorized representative shall give Supplier reasonable prior notice of an intent to audit.

- 21.2. If ORGANON deems that an audit conducted by ORGANON or its authorized representative pursuant to the preceding Paragraph reveals any control deficiency in Supplier's internal controls, Supplier shall promptly remedy all deficiencies which ORGANON has identified and submit to ORGANON documented procedures reflecting the changes being implemented.

## **ARTICLE 22 ELIMINATION OF ANTISOCIAL FORCES**

- 22.1. Each party represents and guarantees to the other party that neither the party nor its officers (meaning board members (*torishimariyaku*), executive officers (*shikkouyaku*), or equivalents thereof who substantively hold a controlling interest of the party) is or will be an organized crime group (*boryokudan*), a member of an organized crime group, a former member of an organized crime group for whom five years have not yet passed since leaving the organized crime group, an associate member of an organized crime group, a company related to an organized crime group, a corporate extortionist (*sokaiya*) and the like, a socially-branded racketeering organization (*shakaiundoto-hyobo-goro*), an organized crime-related specialist (*tokushuchino-boryokushudan*) and the like, or any other person or organization equivalent thereto (collectively "Gang Members"), and does not and will not have any:

- ① Relationship in which its management is deemed to be controlled by a Gang Member;
- ② Relationship in which its management is deemed to be substantially involved with a Gang Member;
- ③ Relationship in which it is deemed to be wrongfully making use of a Gang Member, including making use of a Gang Member for the purpose of obtaining a wrongful benefit for the party itself or a third party or causing damage to a third party;
- ④ Relationship in which it is deemed to be involved with a Gang Member by providing funds or any other benefit, etc. thereto; or
- ⑤ Socially reprehensible relationship with a Gang Member.

- 22.2. If it is found that either party has breached the guarantee set forth in the preceding paragraph, the non-breaching party may terminate the Individual Agreement without notice.
- 22.3. If it is found that a contracting party, its agent or broker is a Gang Member or has any of the relationships listed under the items of Paragraph 1 when the party enters into a subcontract or outsourcing agreement, etc. (“Associated Agreement”) with a third party in connection with the Individual Agreement, the non-breaching party may ask the party to immediately terminate the Associated Agreement and/or take any other necessary measures. If the breaching party fails to respond to such request without reasonable grounds, the non-breaching party may terminate the Individual Agreement without notice.
- 22.4. If the Individual Agreement is terminated by either party pursuant to Paragraph 2 or 3, the terminating party shall not be liable, or pay any compensation, for any damages that the other party may incur, and the other party shall be liable for any damages that the terminating party may incur. The amount of the liability will be determined upon consultation between the parties.

## **ARTICLE 23 TERMINATION OF AGREEMENT**

- 23.1. ORGANON shall have the right to terminate the Individual Agreement, in part or in whole, upon not less than thirty (30) days’ prior written notice to Supplier. In such event, ORGANON and Supplier shall make decisions concerning the settlement of the purchase price through mutual consultation.
- 23.2. ORGANON shall have the right to terminate the Individual Agreement, in part or in whole, without prior notice, immediately upon the occurrence of any of the following events involving Supplier, regardless of whether or not such event arises due to any reason attributable to Supplier:
- ① Supplier breaches the Individual Agreement;
  - ② Supplier bounces notes or checks, or otherwise suspends payments;
  - ③ A petition for a provisional attachment, attachment, provisional disposition, auction, etc., involving Supplier is filed;
  - ④ A petition for bankruptcy, civil rehabilitation, corporate reorganization, special liquidation or other similar proceedings is filed by or against Supplier; or
  - ⑤ Any event similar to any of the foregoing, which adversely affects Supplier’s credibility, occurs.
- 23.3. Termination of the Individual Agreement pursuant to this Agreement shall not preclude ORGANON’s damage compensation claims against Supplier.

## **ARTICLE 24 SURVIVAL**

The provisions of the following Articles hereof shall survive, and remain effective



after, the termination of the Individual Agreement due to completion of performance, termination, etc.: Article 8 (Quality Assurance); Article 9 (Liability for Non-Conforming Item); Article 10 (Confidentiality Obligation); Article 11 (Compensation for Damages); Article 12 (Product Liability); Article 13 (Infringement on Third Parties' Rights); Article 15 (Compliance, Ethics, and Conflict of Interest); Article 20 (Publicity); Article 21 (Audit Rights); Article 24 (Survival); Article 25 (Governing Law) and Article 26 (Dispute Resolution).

#### **ARTICLE 25 GOVERNING LAW**

The validity, construction, performance and enforceability of these Terms & Conditions, the Individual Agreement and any and all of the transactions relating thereto shall be governed by and construed in accordance with the laws of Japan.

#### **ARTICLE 26 DISPUTE RESOLUTION**

The parties hereto agree that the Tokyo District Court shall have exclusive jurisdiction as the court of first instance over any lawsuit involving the Individual Agreement or any transaction relating thereto.

#### **ARTICLE 27 HEADINGS**

Headings of articles used in these Terms & Conditions are inserted for reference purposes only, and shall not be used in connection with the construction of these Terms & Conditions.

#### **ARTICLE 28 RESOLUTION THROUGH CONSULTATION**

ORGANON and Supplier shall resolve through mutual consultation conducted in good faith any matter not set forth in the Individual Agreement or any dispute that arises in connection with the Individual Agreement.

#### **ARTICLE 29 REPORTING ADVERSE EVENTS AND QUALITY COMPLAINTS**

- 29.1. Whereas applicable, Supplier will transmit any Adverse Events (AEs), Product Quality Complaints (PQCs), and other reportable information (including without limitation, local law reporting requirements, health authority reporting guidance etc.) related to Organon medicinal product or medical device within one (1) business day or three (3) calendar days, whichever is shorter, upon receipt from any source.
- 29.2. Supplier and ORGANON will agree on the mode of transmission for safety information, which will be documented in a mutually agreed upon agreement (ie: PV plan, PV agreement, protocol, safety management plan) prior to the commencement of activities.
- 29.3. In situations where collection of adverse events are outside the scope of the services



but the Supplier learns of any Adverse Event or Product Quality Complaint related to Organon product, the Supplier agrees to report the Adverse Event to ORGANON's local Designated Point of Contact (DPOC) <phone #> <fax #, if available>.

- 29.4. An adverse event is untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product or medical device, whether or not considered related to the medicinal product or medical device.
- 29.5. A Product Quality Complaint (PQC) is any communication that describes a potential defect related to the identity, strength, quality, purity, or performance of a product identified by an external customer. This includes potential device or device component malfunctions.
- 29.6. Other reportable information includes but not limited to worsening of existing symptoms, new disease, abuse, misuse, overdose, accidental exposure, medication errors, off label use and drug exposure during pregnancy.

**ORGANON K.K. STANDARD TERMS & CONDITIONS  
PURCHASE OF SERVICES (VERSION 15, April 12, 2021)**

The Terms & Conditions set forth below shall apply to each service agreement by and between ORGANON K.K. as a purchaser (hereinafter referred to as “ORGANON”), and the other party thereto as a contractor (hereinafter referred to as “Supplier”) concerning any service (hereinafter referred to as the “Service”) to be provided by Supplier to ORGANON and purchased by ORGANON from Supplier.

**ARTICLE 1 FORMATION OF THE SALE AND PURCHASE AGREEMENT**

- 1.1 A service agreement (hereinafter referred to as the “Individual Agreement”) by and between Supplier and ORGANON concerning the Service shall become effective (i) upon Supplier’s issuance to ORGANON of written notice of Supplier’s acceptance of ORGANON’s written purchase order in ORGANON’s prescribed form, which sets forth the Service’s details, with or without any deliverable (hereinafter referred to as “Deliverable”) in connection with the Service, order date, period of performance, if with Deliverable, delivery due date and delivery location, transaction price, payment due date and other specific information necessary for the performance of the Service; or (ii) as of the date which is three (3) business days after the date on which Supplier receives the written purchase order, if Supplier fails to issue written notice of rejection of the written purchase order within such three (3) business day period. These Terms & Conditions and the provisions set forth in the applicable written purchase order shall constitute the provisions of the Individual Agreement. If ORGANON’s written purchase order notes the date on which ORGANON wishes to have the Services delivered, such date shall be deemed to mean, in principle, the Deliverable’s delivery due date or the Service’s completion-of-performance date.
- 1.2 If, after ORGANON’s issuance to Supplier of a written purchase order described in the preceding Paragraph, Supplier provides ORGANON with notice of other terms and conditions (hereinafter referred to as “Supplier’s Terms & Conditions”), which are either different from these Terms & Conditions or which include additional terms and conditions, no Individual Agreement shall become effective, except when ORGANON provides Supplier with written notice of ORGANON’s acceptance of Supplier’s Terms & Conditions.
- 1.3 Notwithstanding the provisions of the preceding Paragraph, if Supplier commences the Service prior to ORGANON’s issuance to Supplier of written notice of ORGANON’s acceptance of Supplier’s Terms & Conditions and ORGANON acknowledges such commencement of the Service, Supplier’s Terms & Conditions shall be null and void, and these Terms & Conditions and the provisions set forth in

the applicable written purchase order shall constitute the provisions of the Individual Agreement.

- 1.4 The Service's transaction price to be set forth in ORGANON's written purchase order shall be determined through consultation by and between ORGANON and Supplier based on the written estimates submitted by Supplier to ORGANON; provided, however, that, in the event that the Service's transaction price has previously been separately agreed upon by and between ORGANON and Supplier, ORGANON shall set forth in its written purchase order the transaction price which conforms to such agreement.
- 1.5 The Service's transaction price to be set forth in ORGANON's written purchase order shall include any expense necessary to perform the Service and be the price as the Deliverable will be delivered to the designated delivery location, which includes the packaging, transportation and all other expenses of the Deliverable (net of consumption taxes); provided, however, that, if ORGANON's written purchase order sets forth price-related terms that are different from the foregoing, such terms shall prevail.
- 1.6 The provisions of an Individual Agreement may be amended upon prior consultation by and between ORGANON and Supplier; the procedures for making such amendments shall be the same as those procedures described in Paragraph 1.1 above.

## **ARTICLE 2 PERFORMANCE OF THE SERVICE AND DELIVERY OF THE DELIVERABLE**

- 2.1 Immediately upon the occurrence of any event which prevents, or may prevent, Supplier from completing the Service in whole or in part within the period of performance, Supplier shall notify ORGANON of the reason therefor, the estimated date of completion, etc., and comply with ORGANON's instructions. If the Service is not completed within the period of performance due to a cause for which Supplier should be held responsible, ORGANON shall have the right to demand that Supplier pay compensation for damages suffered by ORGANON as a result thereof.
- 2.2 Supplier shall not cease the Service without a valid cause or the consent of ORGANON.
- 2.3 Supplier shall, in compliance with the provisions of the Individual Agreement, deliver the Deliverable, together with a delivery notice and other necessary documents in the form prescribed by ORGANON, on or before the delivery due date. If ORGANON wishes to change the delivery due date or other delivery conditions for its convenience, ORGANON shall hold prior consultations with Supplier, and Supplier shall cooperate with ORGANON.
- 2.4 Supplier shall comply with instructions, if any, issued by ORGANON concerning the method of packaging and transporting the Deliverable, etc.
- 2.5 If, in connection with the delivery of the Deliverable, preparations for accepting

heavy, hazardous, etc., deliverables are deemed to be required, Supplier shall deliver prior notice to the address designated by ORGANON setting forth the delivery date/time and special handling instructions.

- 2.6 Immediately upon the occurrence of any event which prevents, or may prevent, Supplier from delivering the Deliverable in whole or in part on or before the delivery due date, Supplier shall notify ORGANON of the reason therefor, the estimated delivery date, etc., and comply with ORGANON's instructions. If the Deliverable is not delivered on or before the delivery due date due to a cause for which Supplier should be held responsible, ORGANON shall have the right to demand that Supplier pay compensation for damages suffered by ORGANON as a result thereof.
- 2.7 Supplier shall obtain ORGANON's prior consent, if Supplier wishes to deliver the Deliverable prior to the delivery due date.

### **ARTICLE 3 SAFETY, DISASTER PREVENTION AND ENVIRONMENTAL PROTECTION MEASURES TO BE TAKEN AT THE TIME OF PERFORMANCE OF THE SERVICE AND DELIVERY OF THE DELIVERABLE**

- 3.1 Supplier shall perform the Service and deliver the Deliverable in compliance with the applicable laws, ordinances and regulations, as well as various rules and instructions prescribed or issued by ORGANON, taking into consideration issues relating to safety, disaster prevention and environmental protection.
- 3.2 Whenever Supplier causes a third party designated by Supplier to perform the Service and deliver the Deliverable, Supplier shall cause such party to comply with Supplier's obligations set forth in the preceding Paragraph.
- 3.3 Supplier shall immediately notify ORGANON upon the occurrence of any loss, accident or environmental pollution which affects ORGANON, Supplier or any third party arising from the performance of the Service and the delivery of the Deliverable.
- 3.4 If the loss, accident or environmental pollution referenced in the preceding Paragraph occurs due to a cause for which Supplier should be held responsible, Supplier shall, at Supplier's cost and as Supplier's responsibility, urgently take appropriate remedial measures. In addition, Supplier shall pay compensation for damages suffered by ORGANON or any third party as a result of such loss, accident or environmental pollution.

### **ARTICLE 4 USE OF OFFICE AND EQUIPMENT**

- 4.1 ORGANON shall cause Supplier to use office and equipment, fixture, furniture, material, information etc. (hereinafter collectively referred to as the "Equipment, Etc.") free of charge to the extent necessary for Supplier to perform the Service. In the event that Supplier performs the Service at ORGANON's office, ORGANON shall pay the

utility cost incurred in connection therewith.

- 4.2 Supplier shall use office and Equipment, Etc. in compliance with the applicable laws, ordinances and regulations, as well as various rules and instructions prescribed or issued by ORGANON, taking into consideration issues relating to safety, disaster prevention and environmental protection, with the care of a good manager.
- 4.3 Supplier shall use office and Equipment, Etc. for the sole purpose of its performance of the Service, cease the use and return such Equipment, Etc. to ORGANON after the completion of the Service or upon ORGANON's request to cease the use and return such Equipment, Etc.

## ARTICLE 5 ACCEPTANCE INSPECTION

- 5.1 ORGANON shall, immediately after its receipt of the delivered Deliverable, conduct an acceptance inspection in accordance with the inspection method and inspection standards previously prescribed by ORGANON and Supplier through mutual consultation, and ORGANON shall notify Supplier of the results thereof without delay.
- 5.2 If ORGANON discovers anything not conforming to the terms of this Agreement or any Individual Agreement regarding the quality or quantity of the Product (the “**Non-Conforming Item**”) as a result of the acceptance inspection referenced in the preceding Paragraph, Supplier shall deliver the missing or replacement Product, repair the Product containing Non-Conforming Item (the “**Substandard Product**”), or take other measures in compliance with ORGANON’s instructions within the period separately specified by ORGANON, and ORGANON shall inspect or re-inspect the Product so delivered or repaired.
- 5.3 In the event, despite ORGANON’s instructions referenced in the preceding Paragraph, Supplier fails to deliver the missing or replacement Product or repair the Substandard Product within the period specified by ORGANON, or in the event that the reason for the Substandard Product is based on a minor defect and it is recognized that the Substandard Product can be used through ORGANON innovations, ORGANON may specially adopt and receive the Substandard Product as a special exception limited to this Substandard Product, conditionally upon the reduction of the purchase price amount in accordance with the degree of the non-conformity.
- 5.4 If ORGANON requests that Supplier retrieve the Substandard Deliverable, Supplier shall retrieve the Substandard Deliverable within the period separately prescribed by ORGANON; during such period, ORGANON shall keep custody of the Substandard Deliverable with the care of a good manager.
- 5.5 Upon the expiration of the period referenced in the preceding Paragraph, ORGANON shall have the right to return the Substandard Deliverable to Supplier, or dispose of the Substandard Deliverable with Supplier’s consent. In such event, Supplier shall pay the cost and expenses incurred in connection with such return or disposal.

- 5.6 Nothing in this Article shall prejudice ORGANON's right to claim damage compensations from Supplier.

## **ARTICLE 6 TRANSFER OF OWNERSHIP**

Ownership of the Deliverable shall be transferred from Supplier to ORGANON when the Deliverable passes the acceptance inspection or when a decision is made to accept the Deliverable on a limited and exceptional basis.

## **ARTICLE 7 RISK OF LOSS, ETC.**

(i) Until ownership is transferred pursuant to the provisions of the preceding Article, Supplier shall bear the risk of loss of or damage to the Deliverable due to any reason not attributable to neither of the parties hereto, including but not limited to force majeure and other unavoidable events, and ORGANON may, at its option, refuse to pay the purchase price for such Product or terminate the Individual Agreement in relation to such Product; and (ii) after such transfer of ownership, ORGANON shall bear such risk and shall not be entitled to demand the delivery of the replacement or the repair of the Product by reason of the loss or damage. Notwithstanding the foregoing, after the Deliverable is delivered and before the ownership is transferred, ORGANON shall keep custody of the Deliverable with the care of a good manager.

## **ARTICLE 8 PAYMENT**

- 8.1 Supplier shall submit to ORGANON an accurately prepared invoice after the Service is completed.
- 8.2 ORGANON shall pay the purchase price of the Service, which has been completed, within 90 days, after the receipt of the invoice referenced in the preceding Paragraph, by making a remittance to an account at a financial institution designated by Supplier. Notwithstanding the foregoing, if ORGANON's written purchase order sets forth payment terms which are different from the foregoing, ORGANON's payment shall be made in accordance with such payment terms set forth in ORGANON's written purchase order.
- 8.3 If any payment pursuant to this Agreement is made by way of by making a remittance to an account at a financial institution, such payment shall be deemed to become effective upon the payer having completed a remittance request at the remitting bank.
- 8.4 Upon submitting an invoice, Supplier shall attach a document with a valid issue date pursuant to the expense policy set forth separately by ORGANON. In case ORGANON requests, Supplier also shall provide ORGANON with evidentiary materials (invoices issued by its subcontractor etc.) to show the cost paid to the subcontractor is reasonable. If Supplier does not comply with the above, ORGANON has a right to withhold payments to a reasonable extent.

## **ARTICLE 9 DUTY OF CARE OF A GOOD MANAGER**

Supplier shall perform the Service with the care of a good manager in compliance with ORGANON's instructions.

## **ARTICLE 10 QUALITY ASSURANCE, DATA INTEGRITY**

- 10.1 Supplier warrants that the Deliverable's quality shall be such that it will comply with the specifications designated by ORGANON, the laws, regulations and safety standards applicable to the Deliverable as well as the purposes intended by ORGANON.
- 10.2 Supplier warrants that the Service shall be performed in conformity with the laws, regulations, safety standards and industry standards applicable to the Service.
- 10.3 Supplier shall create the quality management standards and methods of inspection, etc. for the Deliverable to warrant the quality of the Deliverable, and thereby carry out the quality management and inspection, etc. in a responsible manner.
- 10.4 Supplier endeavors to establish the quality management system and carries out an adequate quality management in the case of the Deliverable newly designed, the alteration of the design, or the alteration of the process.
- 10.5 ORGANON may, when it finds it necessary to do so, request Supplier to provide the document which warrants the quality of the Deliverable.
- 10.6 Supplier shall keep the drawing, specification and plan of the quality of the Deliverable, technical information materials of the manufacturing, the guideline and result of the examination or inspection, and the respective originals of the rules (including anything equivalent to the originals), etc. pursuant to the document keeping standards, and respond promptly if ORGANON requests Supplier to submit these documents.
- 10.7 If the level concerning the quality of the Service is agreed upon by and between ORGANON and Supplier, Supplier warrants that its performance of the Service shall conform to such agreement.
- 10.8 Any documentation or data relevant to activities performed, including without limitation any GMP documentation, must be attributable, original, accurate, legible, complete, controlled, retrievable, and safe from intentional or unintentional manipulation or loss. These items are required throughout the retention period of such data / documentation.

## **ARTICLE 11 LIABILITY FOR NON-CONFIRMING ITEM**

- 11.1 If ORGANON discovers Non-Conforming Item not discovered in the inspection under Article 5, Paragraph 1 that has not arisen due to any reason attributable to ORGANON, ORGANON may, within one (1) year from the time ORGANON becomes aware of such Non-Conforming Item, request Supplier to deliver the replacement Product, repair



the Non-Conforming Item, or reduce the purchase price amount (or refund the payment price).

- 11.2 Nothing in the preceding Paragraph shall prejudice ORGANON's right to claim damage compensations from Supplier.
- 11.3 Even after the expiration of the period referenced in the Paragraph 1, Supplier shall pay compensation for damages suffered by ORGANON due to a material Non-Conforming Item for which Supplier should be held responsible.

## **ARTICLE 12 CONFIDENTIALITY OBLIGATION**

- 12.1 Supplier shall not disclose or divulge to any third party the fact that the Individual Agreement has been entered into, any of the terms and conditions of the Individual Agreement, or information concerning ORGANON disclosed or obtained in connection with the performance of the Individual Agreement (hereinafter collectively referred to as the "Confidential Information").
- 12.2 Supplier shall not use the Confidential Information for any purpose other than its performance of the Individual Agreement.
- 12.3 Notwithstanding the provisions of the preceding two (2) Paragraphs, Supplier's obligations under the preceding two (2) Paragraphs shall not apply to any information which can be proved to constitute information described in one of the following Items:
  - ① Information which was already in Supplier's possession when it is disclosed by or obtained from ORGANON;
  - ② Information which was already publicly known or used when it is disclosed by or obtained from ORGANON;
  - ③ Information which becomes publicly known or used, due to causes for which Supplier should not be held responsible, after it is disclosed by or obtained from ORGANON;
  - ④ Information which is legally obtained by Supplier without any confidentiality obligation from a third party which has the proper right to make the disclosure to Supplier; or
  - ⑤ Information which is independently developed by Supplier, after Confidential Information is disclosed by or obtained from ORGANON, without any relation to the disclosed Confidential Information.

## **ARTICLE 13 COMPENSATION FOR DAMAGES**

If, in connection with the performance of the Individual Agreement, ORGANON suffers damages due to causes for which Supplier should be held responsible, Supplier shall pay ORGANON compensation for such damages.

## **ARTICLE 14 PRODUCT LIABILITY**

- 14.1 If any incident occurs due to a defect (i.e., any “defect” as such term is defined in Article 2, Paragraph 2, of the Product Liability Law of Japan; the same shall apply hereinafter) in the Deliverable, ORGANON and Supplier shall cooperate with each other in order to investigate its cause.
- 14.2 Supplier shall notify ORGANON immediately and endeavor to minimize damages if (i) Supplier receives notice that the Deliverable is actually, or may potentially be, defective; or (ii) Supplier receives from a third party a claim for compensation for damages arising from any defect in the Deliverable.
- 14.3 If ORGANON suffers any loss arising from any defect in the Deliverable, due to damages caused by the Deliverable or any product incorporating the Deliverable and suffered by ORGANON or any third party (including situations where ORGANON pays damage compensation to such third party), Supplier shall pay ORGANON compensation for damages which have reasonable causation (*soutou inga kankei*) with the defect (including attorneys’ fees, investigation expenses, etc.); provided, however, that the foregoing shall not apply in the event described in either of the following Items:
- ① The defect in the Deliverable could not be identified by the scientific technologies which existed when the Deliverable was delivered; or
  - ② The defect arose solely from Supplier’s compliance with ORGANON’s instructions, and Supplier did not commit any negligence that contributed to the existence of the defect.
- 14.4 Supplier shall, upon mutual consultation with ORGANON, obtain, at Supplier’s cost, general liability insurance in an amount which is sufficient to cover the obligation to pay third parties compensation for damages arising from the use or sale of the Deliverable.

## ARTICLE 15 INFRINGEMENT ON THIRD PARTIES’ RIGHTS

- 15.1 Supplier warrants that, in its performance of the Service, neither the Deliverable, nor its manufacturing method, infringes on any third party’s patent right, utility model right, design right, trademark right or any other industrial property right, copyright or any other intellectual property right (hereinafter collectively referred to as the “Intellectual Property Right, Etc.”). Supplier shall provide ORGANON with immediate notice if any dispute arises or may arise in connection with any third party’s Intellectual Property Right, Etc., resolve such dispute at Supplier’s cost and as Supplier’s responsibility, and hold ORGANON harmless from any and all damages whatsoever.
- 15.2 Supplier warrants that, in its performance of the Service, neither the Deliverable, nor its manufacturing method, utilizes any third party’s trade secret. Supplier shall provide ORGANON with immediate notice if any dispute arises or may arise in connection with any third party’s trade secret, resolve such dispute at Supplier’s cost and as

Supplier's responsibility, and hold ORGANON harmless from any and all damages whatsoever.

- 15.3 ORGANON shall provide Supplier with immediate notice if ORGANON receives any claim from a third party, or if a lawsuit is brought against ORGANON by a third party, concerning the Deliverable's infringement on such third party's Intellectual Property Right, Etc., or the Deliverable's use of such third party's trade secret, and Supplier shall resolve such dispute at Supplier's cost and as Supplier's responsibility. ORGANON shall cooperate with Supplier to resolve such dispute upon Supplier's request in connection with the resolution of such dispute.

## **ARTICLE 16 INTELLECTUAL PROPERTY RIGHTS**

- 16.1 Any copyrights (including such rights as provided in Articles 27 and 28 of the Copyright Law of Japan) of the Deliverable which has been delivered to ORGANON shall belong to ORGANON. Supplier shall not exercise its moral rights of author concerning the Deliverable against ORGANON or any third party.
- 16.2 In the event that Supplier invents, contrives or creates designs etc. (hereinafter collectively referred to as the "Invention, Etc."), Supplier shall immediately notify ORGANON of such Invention, Etc. ORGANON and Supplier shall make decisions concerning the ownership and the exercise of such Invention Etc. through mutual consultation. The same shall apply to Invention Etc. which has been jointly made by ORGANON and Supplier.

## **ARTICLE 17 ASSIGNMENT OF RIGHTS AND OBLIGATIONS**

- 17.1 Neither ORGANON, nor Supplier, shall assign, or create security interest on, all or a part of its rights, or delegate all or a part of its obligations, under the Individual Agreement, without the other party's prior written consent; provided, however, that no assignment of any right under this Agreement or the Individual Agreement constitutes a breach of this Article if the party who intends such assignment (i) notifies the assignee of the existence and contents of the restrictions as set out in this Article in advance of such assignment in writing and (ii) delivers to the other party a certified copy of the written notice.
- 17.2 In the event that Supplier, pursuant to the preceding Paragraph and with the prior written consent of ORGANON, subcontract all or a part of the Service to a third party, Supplier shall impose on such third party the same obligations as Supplier's obligations under the Individual Agreement and shall be liable for all the compliance and performance of such third party. In addition, Supplier shall not be discharged from its obligations under the Individual Agreement.

## **ARTICLE 18 COMPLIANCE, ETHICS, AND CONFLICT OF INTEREST**

- 18.1 Supplier agrees that in its performance under the Individual Agreement, it shall adhere to all applicable laws, regulation, ordinances and guidance, business practices that are in accordance with the spirit of such applicable laws and ethical principles, and following provisions:
- ① Supplier agrees that all transactions in connection with the Individual Agreement will be accurately reflected in its books and records, and that no funds or other assets shall be paid directly or indirectly to government officials or persons acting on their behalf for the purpose of influencing government decisions or actions with respect to ORGANON's business; and
  - ② Supplier further agrees to conduct its activities under the Individual Agreement and its dealings with ORGANON, subcontractors, and third parties so as to avoid loss or embarrassment to ORGANON due to any real or apparent conflict of interest, and to require that all subcontractors comply with such policy in connection with the Individual Agreement.
- 18.2 ORGANON shall have the right to terminate the Individual Agreement upon violation of business practices referenced in the preceding Paragraph on the part of the Supplier, its employees, agents, representatives, subcontractors, consultants, or temporary contractors.

## **ARTICLE 19 ORGANON'S BUSINESS PARTNER CODE OF CONDUCT**

2. ORGANON endeavors to hold itself and its Supplier to the highest ethical and compliance standards, including basic human rights, encouraging fair and equal treatment for all persons, the provision of safe and healthy working conditions, respect for the environment, the adoption of appropriate management systems and the conduct of business in an ethical manner. Without limiting any of Supplier's other obligations hereunder, and without conflicting with or limiting any of the warranties, obligations or other provisions expressly set forth elsewhere in the Individual Agreement, including without limitation its obligations under Article 3.1 hereof, Supplier agrees that it will abide by the letter and spirit of ORGANON's Business Partner Code of Conduct (the "Code"), as in effect from time to time, a copy of which is available at [https://www.organon.com/wp-content/uploads/sites/2/2021/05/Business-Partner-Code-Of-Conduct\\_v1.pdf](https://www.organon.com/wp-content/uploads/sites/2/2021/05/Business-Partner-Code-Of-Conduct_v1.pdf)
- 19.1 Supplier agrees that it will provide all documentation reasonably requested by ORGANON to demonstrate compliance with the Code. In the event of a conflict between the obligations in this Article 19.1 and the Code, on the one hand, and any other provision in the Individual Agreement, on the other hand, such other provision of the Individual Agreement shall control (but only to the extent of the conflict).
- 19.2 ORGANON reserves the right, in its sole discretion, to audit Supplier's operations, books and records to ensure compliance with the Code. ORGANON will provide reasonable advance notice of such an audit, and may conduct this audit on its own or using a third-party auditor of its choosing. Supplier shall acknowledge receipt of

ORGANON's notice as promptly as practicable after receipt of such notice and will confirm the date on which the audit will occur within fourteen (14) days after receipt of such notice. ORGANON or its third-party auditor may interview Supplier's employees as part of or in connection with the audit. This audit right shall be in addition to any other audit rights granted in the Individual Agreement.

- 19.3 In the event an audit identifies a non-conformance by Supplier with the Code, Supplier will promptly take corrective action to remedy the non-conformance. ORGANON reserves the right to approve all corrective actions. Corrective actions shall be implemented by Supplier at Supplier's expense. ORGANON will endeavor, whenever practicable, to work with Supplier to remedy the issue and put in place a corrective action plan.
- 19.4 In the event Supplier refuses to allow an audit, or fails or refuses to take corrective action, then in addition to any other remedy available to it under the Individual Agreement, at law or in equity, ORGANON reserves the right to terminate the Individual Agreement in the event Supplier fails to cure such refusal or failure within ninety (90) days after written notice from ORGANON.

## **ARTICLE 20 SUPPLIER EXPECTATIONS**

Without limiting any of Supplier's other obligations hereunder and without limiting any of the express warranties or obligations agreed to elsewhere in the Individual Agreement, including without limitation its obligations under Article 3.1 hereof, ORGANON expects that Supplier will abide by the letter and spirit of ORGANON's Supplier Performance Expectations, as in effect from time to time, a copy of which is available at <https://www.organon.com/wp-content/uploads/sites/2/2021/04/Organon-Supplier-Performance-Expectations.pdf>

In the event of a conflict between the obligations in this Article and ORGANON's Supplier Performance Expectations, on the one hand, and any other provision in the Individual

Agreement, on the other hand, such other provision of the Individual Agreement shall control (but only to the extent of the conflict).

## **ARTICLE 21 EXCLUDED ENTITIES**

- 21.1 The term "Violation" as used in this Article shall mean that either Supplier, or any of its officers or directors has been (each of (1), (2) and (3) collectively the "Exclusions Lists"):

(1) convicted of any of the felonies identified among the exclusion authorities listed on the U.S. Department of Health and Human Services, Office of Inspector General (OIG) website (<http://oig.hhs.gov/exclusions/authorities.asp>), including 42 U.S.C. 1320a-7(a);

(2) identified in the OIG List of Excluded Individuals/Entities (LEIE) database (<http://oig.hhs.gov/fraud/exclusions.asp>) or the U.S. General Services Administration's list of Parties Excluded from Federal Programs (<https://www.sam.gov/SAM/>); or

(3) listed by any US Federal agency as being suspended, debarred, excluded, or otherwise ineligible to participate in Federal procurement or non-procurement programs.

- 21.2 Supplier represents and warrants that prior to the date of this Agreement, it has screened itself, and its officers and directors against the Exclusions Lists and that it has informed ORGANON whether it, or any of its officers or directors has been in Violation. After the execution of this Agreement, Supplier shall notify ORGANON in writing immediately if any such Violation occurs or comes to its attention. ORGANON shall also have the right, in its sole discretion, to terminate the Individual Agreement as well as other agreements then effective between ORGANON and Supplier if any, immediately in the event of any such Violation.

## **ARTICLE 22 SELF-CERTIFICATION DENIED PARTIES CLAUSES**

- 22.1 Supplier represents and warrants that it is not nor any of its legal representatives, as applicable, are listed on any of the U.S. or EU denied parties lists, or any other denied parties list issued by another jurisdiction which is applicable to the products or technical data supplied under the Agreement, as notified by ORGANON to it from time to time, all of the foregoing collectively referred to as “Denied Parties Lists”. As of the date of this Memorandum, the Denied Parties Lists consist of the U.S. Treasury Department (<https://home.treasury.gov/>)’s List of Specially Designated Nationals and Blocked Persons (the “SDN List”), the U.S. Commerce Department (<https://www.bis.doc.gov/>)’s Denied Persons List and Entity List, and the Consolidated List of Persons, Groups and Entities Subject to EU Financial Sanctions ([http://eeas.europa.eu/cfsp/sanctions/consol-list\\_en.htm](http://eeas.europa.eu/cfsp/sanctions/consol-list_en.htm)). Supplier further represents and warrants that it is not directly owned by 50% or more by a person or an entity listed on the SDN List. Supplier further represents and warrants that it shall notify ORGANON in writing immediately if it or any of its legal representatives become listed on any of the U.S. or EU denied parties lists or if it becomes owned by 50% or more by a person or an entity listed on the SDN List.
- 22.2 In case of an inaccuracy in or a breach of the representations and warranties provided in the preceding paragraph, ORGANON has the right, in its sole discretion, to terminate the Agreement immediately and without penalty to ORGANON. Supplier agrees to indemnify and hold harmless ORGANON for any inaccuracy or breach of the representations and warranties provided in the preceding paragraph.
- 22.3 This Article shall survive termination or cancellation of the Agreement.



## **ARTICLE 23 PUBLICITY**

Supplier agrees not to advertise or otherwise make known to others any information regarding the terms and conditions, or existence of the Individual Agreement. Supplier further agrees not to use or reference in any advertising, sales promotion, press release or other communication, any company or representative name, endorsement, direct or indirect quote, code, drawing, logo, trademark, specification, or picture of ORGANON (ORGANON K.K., and its affiliates ((i) any corporation or business entity of which fifty percent (50%) or more is owned directly or indirectly by ORGANON K.K.; or (ii) any corporation, or business entity that owns directly or indirectly fifty percent (50%) or more of ORGANON K.K., or (iii) any corporation, or business entity under the direct or indirect control of any party described in (i) or (ii))) without the prior written consent of ORGANON.

## **ARTICLE 24 AUDIT RIGHTS**

- 24.1 Supplier's records, which shall include, but not be limited to, accounting records, time sheets, written policies and procedures, test results, reports, correspondence, memoranda and any other documentation relating to the performance of the Individual Agreement, shall be open to inspection and subject to audit and/or reproduction, during normal working hours, by ORGANON or its authorized representative to the extent necessary to adequately evaluate claims submitted by Supplier, as required by governmental authorities or as desirable for any other valid business purpose. For the purpose of such audits, inspections, examinations and evaluations, ORGANON or its authorized representative shall have access to the foregoing records beginning on the effective date and continuing until seven (7) years after the satisfaction of Supplier's obligations under the Individual Agreement. In addition, Supplier shall provide adequate and appropriate workspace for ORGANON or its authorized representatives to conduct such audit. ORGANON or its authorized representative shall give Supplier reasonable prior notice of an intent to audit.
- 24.2 If ORGANON deems that an audit conducted by ORGANON or its authorized representative pursuant to the preceding Paragraph reveals any control deficiency in Supplier's internal controls, Supplier shall promptly remedy all deficiencies which ORGANON has identified and submit to ORGANON documented procedures reflecting the changes being implemented.

## **ARTICLE 25 ELIMINATION OF ANTISOCIAL FORCES**

- 25.1 Each party represents and guarantees to the other party that neither the party nor its officers (meaning board members (*torishimariyaku*), executive officers



(*shikkouyaku*), or equivalents thereof who substantively hold a controlling interest of the party) is or will be an organized crime group (*boryokudan*), a member of an organized crime group, a former member of an organized crime group for whom five years have not yet passed since leaving the organized crime group, an associate member of an organized crime group, a company related to an organized crime group, a corporate extortionist (*sokaiya*) and the like, a socially-branded racketeering organization (*shakaiundoto-hyobo-goro*), an organized crime-related specialist (*tokushuchino-boryokushudan*) and the like, or any other person or organization equivalent thereto (collectively “Gang Members”), and does not and will not have any:

- ① Relationship in which its management is deemed to be controlled by a Gang Member;
- ② Relationship in which its management is deemed to be substantially involved with a Gang Member;
- ③ Relationship in which it is deemed to be wrongfully making use of a Gang Member, including making use of a Gang Member for the purpose of obtaining a wrongful benefit for the party itself or a third party or causing damage to a third party;
- ④ Relationship in which it is deemed to be involved with a Gang Member by providing funds or any other benefit, etc. thereto; or
- ⑤ Socially reprehensible relationship with a Gang Member.

25.2 If it is found that either party has breached the guarantee set forth in the preceding paragraph, the non-breaching party may terminate the Individual Agreement without notice.

25.3 If it is found that a contracting party, its agent or broker is a Gang Member or has any of the relationships listed under the items of Paragraph 1 when the party enters into a subcontract or outsourcing agreement, etc. (“Associated Agreement”) with a third party in connection with the Individual Agreement, the non-breaching party may ask the party to immediately terminate the Associated Agreement and/or take any other necessary measures. If the breaching party fails to respond to such request without reasonable grounds, the non-breaching party may terminate the Individual Agreement without notice.

25.4 If the Individual Agreement is terminated by either party pursuant to Paragraph 2 or 3, the terminating party shall not be liable, or pay any compensation, for any damages that the other party may incur, and the other party shall be liable for any damages that the terminating party may incur. The amount of the liability will be determined upon consultation between the parties.

## ARTICLE 26 PROTECTION ON PERSONAL INFORMATION

- 26.1 The term “Personal Information” as used in this Article shall mean information relating to individuals that Supplier comes to know in connection with its performance of the Individual Agreement, including such individuals’ names, dates of birth, and other descriptions that could identify specific individuals (including information that may be easily collated with other information to identify specific individuals).
- 26.2 Supplier shall comply with all following Items with respect to Personal Information:
- ① Supplier shall not disclose Personal Information to any third party without the prior written consent of ORGANON;
  - ② Supplier shall not use or process Personal Information for any purpose other than the purpose of performing of the Individual Agreement without the prior written consent of ORGANON;
  - ③ Supplier shall not copy or reproduce Personal Information for any purpose other than the purpose of the performance of the Individual Agreement without the prior written consent of ORGANON, and Supplier shall minimize such copies or reproductions even within the scope of the purpose of performing the Individual Agreement;
  - ④ Supplier shall keep Personal Information under tight control and cause Personal Information to be handled only by its relevant persons, and Supplier shall not take, disclose or leak the Personal Information outside the department or company; and
  - ⑤ Supplier shall take the necessary and appropriate measures against risks relating to Personal Information (including unauthorized access to Personal Information, loss, destruction, interpolation and leakage of Personal Information) in order to ensure that Personal Information is safely controlled.
  - ⑥ In addition to the previous items, Supplier shall comply with all applicable laws, rules and regulations relating to Personal Information and take measures required by those laws, rules and regulations (obtaining consent, or notify etc.) upon processing of Personal Information (including collecting, using, disclosing, providing, retaining and disposing).
- 26.3 Supplier shall, in order to ensure that Personal Information is safely controlled, exercise the necessary and appropriate supervision over its employees, and cause its employees to be thoroughly familiar with and to comply with the obligations set forth in the preceding Paragraph.
- 26.4 Supplier shall, in case of re-entrusting the handling of Personal Information to a third party, exercise the necessary and appropriate supervision over that third party. Supplier may re-entrust the handling of Personal Information to the extent subcontracting of all or a part of the Service to a third party under the Individual Agreement is permitted and according to the terms and conditions of the Individual Agreement.
- 26.5 In the event that an incident, an accident or a dispute between Supplier and a third party, or any other such matter arises in relation to the handling of Personal

Information, Supplier shall immediately notify ORGANON of the matter and seek to deal with and resolve the matter in compliance with ORGANON's instructions. Notwithstanding the foregoing, if it is difficult for Supplier to resolve the matter on its own, ORGANON shall cooperate with Supplier to deal with and resolve the matter.

- 26.6 ORGANON shall have the right, whenever it deems necessary, to cause Supplier to make a written report of items designated by ORGANON as to how Personal Information is being handled.
- 26.7 ORGANON shall have the right, upon obtaining the prior consent of Supplier, enter Supplier's office and inspect and confirm whether the matters provided for in this Article are being complied with, and how Personal Information is being handled.
- 26.8 Supplier shall comply with ORGANON's instructions with respect to the return, deletion, destruction or other handling of Personal Information after the termination of the Individual Agreement.

## **ARTICLE 27 TERMINATION OF AGREEMENT**

- 27.1 ORGANON shall have the right to terminate the Individual Agreement, in part or in whole, upon not less than thirty (30) days' prior written notice to Supplier. In such event, ORGANON and Supplier shall make decisions concerning the settlement of the purchase price through mutual consultation.
- 27.2 Supplier shall not terminate this Agreement or the Individual agreement without the default of ORGANON within the validity term specified in the following Article.
- 27.3 ORGANON shall have the right to terminate the Individual Agreement, in part or in whole, without prior notice, immediately upon the occurrence of any of the following events involving Supplier, regardless of whether or not such event arises due to any reason attributable to Supplier:
  - ① Supplier breaches the Individual Agreement;
  - ② Supplier bounces notes or checks, or otherwise suspends payments;
  - ③ A petition for a provisional attachment, attachment, provisional disposition, auction, etc., involving Supplier is filed;
  - ④ A petition for bankruptcy, civil rehabilitation, corporate reorganization, special liquidation or other similar proceedings is filed by or against Supplier; or
  - ⑤ Any event similar to any of the foregoing, which adversely affects Supplier's credibility, occurs.
- 27.4 Termination of the Individual Agreement pursuant to this Agreement shall not preclude ORGANON's damage compensation claims against Supplier.
- 27.5 In the event that the Individual Agreement is terminated due to completion of performance, termination, etc., Supplier shall immediately return to ORGANON any Equipment, Etc. lent to Supplier by ORGANON under the Individual Agreement.

## **ARTICLE 28 SURVIVAL**

The provisions of the following Articles hereof shall survive, and remain effective after, the termination of the Individual Agreement due to completion of performance, termination, etc.: Article 10 (Quality Assurance); Article 11 (Liability for Non-Conforming Item); Article 12 (Confidentiality Obligation); Article 13 (Compensation for Damages); Article 14 (Product Liability); Article 15 (Infringement on Third Parties' Rights); Article 16 (Intellectual Property Rights); Article 17 (Assignment of Rights and Obligations) Paragraph 2; Article 18 (Compliance, Ethics, and Conflict of Interest); Article 23 (Publicity); Article 24 (Audit Rights); Article 26 (Protection on Personal Information); Article 28 (Survival); Article 29 (Governing Law) and Article 30 (Dispute Resolution).

#### **ARTICLE 29 GOVERNING LAW**

The validity, construction, performance and enforceability of these Terms & Conditions, the Individual Agreement and any and all of the transactions relating thereto shall be governed by and construed in accordance with the laws of Japan.

#### **ARTICLE 30 DISPUTE RESOLUTION**

The parties hereto agree that the Tokyo District Court shall have exclusive jurisdiction as the court of first instance over any lawsuit involving the Individual Agreement or any transaction relating thereto.

#### **ARTICLE 31 HEADINGS**

Headings of articles used in these Terms & Conditions are inserted for reference purposes only, and shall not be used in connection with the construction of these Terms & Conditions.

#### **ARTICLE 32 RESOLUTION THROUGH CONSULTATION**

ORGANON and Supplier shall resolve through mutual consultation conducted in good faith any matter not set forth in the Individual Agreement or any dispute that arises in connection with the Individual Agreement.

#### **ARTICLE 33 REPORTING ADVERSE EVENTS AND QUALITY COMPLAINTS**

- 33.1. Whereas applicable, Supplier will transmit any Adverse Events (AEs), Product Quality Complaints (PQCs), and other reportable information (including without limitation, local law reporting requirements, health authority reporting guidance etc.) related to Organon medicinal product or medical device within one (1) business day or three (3) calendar days, whichever is shorter, upon receipt from any source.
- 33.2. Supplier and ORGANON will agree on the mode of transmission for safety information, which will be documented in a mutually agreed upon agreement (ie: PV

plan, PV agreement, protocol, safety management plan) prior to the commencement of activities.

- 33.3. In situations where collection of adverse events are outside the scope of the services but the Supplier learns of any Adverse Event or Product Quality Complaint related to Organon product, the Supplier agrees to report the Adverse Event to ORGANON's local Designated Point of Contact (DPOC) <phone #> <fax #, if available>.
- 33.4. An adverse event is untoward medical occurrence in a patient or clinical trial subject administered a medicinal product and which does not necessarily have a causal relationship with this treatment. An adverse event can therefore be any unfavourable and unintended sign (e.g. an abnormal laboratory finding), symptom, or disease temporally associated with the use of a medicinal product or medical device, whether or not considered related to the medicinal product or medical device.
- 33.5. A Product Quality Complaint (PQC) is any communication that describes a potential defect related to the identity, strength, quality, purity, or performance of a product identified by an external customer. This includes potential device or device component malfunctions.
- 33.6. Other reportable information includes but not limited to worsening of existing symptoms, new disease, abuse, misuse, overdose, accidental exposure, medication errors, off label use and drug exposure during pregnancy.