Order Form

1. Contract Reference	C96116
2. Data	29 July 2022
3. Buyer	The Secretary of State for Health and Social Care as part of the Crown acting through the UK Health Security Agency, Nobel House, 17 Smith Square, London, SW1P 3HX (the **"Buyer").**
4. Supplier	Fundagao Butantan, company number 133326, of Avenida Vital Brasil,1500 Butanta, Sao·Paulo-SP,05503-900, Brazil (the **"Supplier").**
5. The Contract	The Supplier shall supply the deliverables described below on the terms set out in this Order Form and the attached contract conditions set out at Appendix 1. Unless the context otherwise requires, capitalised expressions used in this Order Form have the same meanings as in Conditions. In the event of any conflict between this Order Form and the Conditions, this Order Form shall prevail. Please do not attach any Supplier terms and conditions to this Order Form as they will not be accepted by the Buyer and may delay conclusion of the Contract. Any purchase order issued by the Buyer in respect of this Agreement does not form part of this Agreement.
6. Delivery	• The Supplier shall deliver the Goods to the Buyer's location stated below or any other agreed point(s) of delivery as the Buyer may advise from time to time. The Buyer's nominated delivery location **("Delivery Location")** is: FAO: [redacted] Goods in Movianto UK Progress Park Bedford United Kingdom • The planned delivery shall be pre-advised by the Supplier to the Buyer's primary delivery contact stated below (individually or collectively be known as the **"Delivery Contact")** at least 48 hours prior to attendance: o Primary delivery contact: [redacted] • Tel: [redacted] o Secondary delivery contract: [redacted] • Email: [redacted] • Tel: [redacted] • The Supplier shall provide the following data when notifying the Delivery Contact: a Supplier name. a Buyer's Purchase Order Number. a Item reference, Supplier's item code, description, and quantity. • The Delivery Contact will confirm: • Booking reference number; • Date and time of service (where applicable); and • Delivery address.

<table>
<tr><td></td><td>Delivery of the Goods shall be considered to have occurred when the Delivery Contact or other authorised representative of the Buyer at the Buyer's Delivery Location has signed the Supplier's delivery note confirming receipt.</td></tr>
<tr><td>7. Specification of Goods and (the "Specification ")</td><td>The Goods shall be supplied in accordance with the following specification (the "Specification")
<table>
<tr><th>Product Code
Batch No.</th><th>Product Description</th><th>QTY</th></tr>
<tr><td>Batch No: 220188
Expiry Date: 01/2025</td><td>Each ml of DAT neutralizes at least 1,000 IU of diphtheria toxin out of at least a total of a 10,000 IU in a 10 ml vial. Each carton contains 5 vials with 10 ml of diphtheria
antitoxin. Diphtheria antitoxin is supplied in 10 ml vial containing an injectable solution of the specific and purified F(ab')2 equine-derived immunoglobulin fractions.</td><td>200 Vials</td></tr>
</table></td></tr>
<tr><td>8. Contract Period and Termination</td><td>The Term shall commence on 29 July 2022 and the Expiry Date shall be 28 October 2022 (the"Term") unless it is otherwise extended or terminated in accordance with the terms and conditions of the Contract.

The Buyer may terminate this Contract for convenience at any time pursuant to clause 11 of Appendix 1 - Short Form Terms and Conditions by giving the Supplier not less than 10 days' written notice.</td></tr>
<tr><td>9. Contract Price</td><td>The maximum value that can be ordered under this Contract is eighteen-thousand, Five hundred and thirty-five US dollars ($18,535.00) (the "Contract Value").

The Contract Price excludes VAT at the applicable rate and any other taxes and is inclusive of freight, data loggers and delivery charges.

For the avoidance of doubt, the Buyer is not committed to pay the Contract Price.

The chares for the Goods shall per Table 2.

Table 2
<table>
<tr><th>Description</th><th>Quantity</th><th>Unit Price</th><th>Total</th></tr>
<tr><td>Diphtheria Antitoxin 100001U/10ml</td><td>200 Vials</td><td>[redacted]</td><td>[redacted]</td></tr>
<tr><td>Origin Charges</td><td>[redacted]</td><td>[redacted]</td><td>[redacted]</td></tr>
<tr><td>Freight</td><td>[redacted]</td><td>[redacted]</td><td>[redacted]</td></tr>
<tr><td>Insurance</td><td rowspan="2">[redacted]</td><td rowspan="2">[redacted]</td><td rowspan="2">[redacted]</td></tr>
<tr><td>Destination Charges</td></tr>
<tr><td></td><td></td><td>Total</td><td>$18,535.00</td></tr>
</table></td></tr>
<tr><td>10. Payment</td><td>Following receipt of the Supplier's countersigned copy of the Contract, the Buyer will send a unique Purchase Order Number.

Payment terms are net 30 days from receipt of a valid invoice.</td></tr>
</table>

	All invoices must be sent for approval and shall include the proof of delivery to the Buyer's designated finance mailbox e-mail: [redacted] and their agreed representative before being submitted for payment. All invoices must be addressed to the Buyer's Account Payable section: United Kingdom Health Security Agency Financial Operations and Control Parton Down Salisbury Wiltshire SP4 OJG The Supplier shall provide compliant invoices that include, as a minimum, a valid Purchase Order Number, Purchase Order Number line-item number (if applicable), Purchase Order Number line description, and the details (name and telephone number) of the Buyer's authorised representative. Non-compliant invoices will be sent back to the Supplier, which may lead to a delay in a payment. Supplier queries regarding payment must be forwarded to the Buyer's Accounts Payable section by email to: [redacted]. All invoices must be sent for approval to the Buyer's designated finance mailbox e-mail: [redacted] and their agreed representative before being submitted for payment. The applicable invoicing process and associated terms are set out in Section 5 of Aooendix 1.
11. Quality Standards	The Supplier must comply with the Specification of the Goods and provide the following information: • Good Manufacturing Practice Certificate - ANNEX A • Certificate of analysis-ANNEX B • Lot release certificate for batch 220188 - ANNEX C • Patient Information Leaflet for batch 220188-ANNEX D • Images of the packaging for antivenom - ANNEX E • A signed and dated statement that the product is Transmissible Spongiform Encephalopathy (TSE) free. The statement will need to confirm that all active and inactive substances present in the unlicensed medicine do not contain materials of animal origin that represent a risk of TSE transmission. If bovine, porcine, or other animal material is used then there must be a declaration that this is from herds that are BSE (or similar disease) free -ANNEX F • Air Waybill and Delivery insurance to provided prior to the Goods have been dispatched.
12. Authorised Representative(s)	The Buyer's Contract Manager is: Name: [redacted] Email: [redacted] The Supplier's Contract Manager is:

	Name: [redacted] Email: [redacted]	
13. Key Performance Indicators	Respond to all operational enquiries within two Working Days - Target: 95% Product relatability and failure rates - Target: Less than 1 % of Goods provided have reported faults. Guarantee to deliver all Goods according to the Delivery Location and lead-time specified on the Purchase Order- Target: 99% of Goods delivered on time and in full.	
14. Address for notices	Buyer: Attention: Jack Moss Address: UK Health Security Agency, Nobel House, 17 Smith Square, London, SW1P 3HX Email: [redacted]	Supplier: Attention: Felipe Altarejo Carvilhe Address: Avenida Vital Brasil,1500 Butanta, Sao Paulo-SP,05503-900, Brazil Email: [redacted]
15. Procedures and Policies	Pricing and individual contact details shall be deemed to be Confidential Information for a period of three (3) years after the expiry or earlier termination of this Contract unless otherwise agreed in writing by the Parties.	

Signed for and on beha[redacted]	Signed for and on behalf of the **Buyer** [redacted]
Full Name: [redacted] Job Title/Role: [redacted] Date Signed [redacted]	Full Name: [redacted] Job Title/Role: [redacted] Date Signed: [redacted]

ANNEX A - Good Manufacturing Practice Certificate

MIN STEAIO DA SAUDE

AG NCIA NACIONAL DE VIGILANCIA SANITAAIA

CERTIF1CADO DE **BOAS** PRATICAS DE FABRICAQAO OE INSUMOS FARMACEUTICOS ATIVOS

LINHA DE **INSUMOS FARMACEUTICOS ATIVOS BIOLOGICOS**

A Agencla Nacional de Vlgiltmcia Sanitarla - ANVISA, per melo da Resoluyao RE nt . de 31/03/2022. publicada em Diario O cial da Uniao (DOU) na data de 04(0412022, certi ca que a empresa abalxo e perlodlcamente inspecionada e monitorada pelo Sistema acional de Vfgilancla Sanilaria e que cumpre com as di,etrizes de Boas PraUcas de Fabrica9ao dada-spe1a leglsla o brasileira, a qual esta em consonancia com as recomendacoes da Organizacao Mundial de Sal.lde.

mpresa: Institute Butantan CNPJ: 61.821.34410001·56
Endereoo: Avenlda Vital Brasil N; 1500, Butanta (predio 41)
Munlcfplo: Sao Paulo UF: SP
Expedien1e(s): 3911692/2, -8
Certificado de Boas Pratlcas de Fabrlcayao de Insumos Farmaceutlcos Atlvos:
Insumos tarmaceu cos alivos biol6glcos: imunoglobullnas hoter6logas.

A presente certllica ao e vallda at o dia 04/04/2024 *e* poc:tera ser cancelada, caso seja comprovado, pela autoridade sanitaria competer1le, o nao cumprimento dos requisilos preoonizados pelas normas vigentes de Boas Pra. cas.

Documento assInado eletronicamooLe por Ana CaroUna Moreira Marino Araujo, Getente-Geral de InSpeftS.Oe Flscaliza o Sanllarla, em 04/04/2022. as 10:36, conforme horarlo oficlal de Brasilia, com rundamento no§ 3vdo art. 4º do Oecreto nv 10.543, de 13 de novembrode 2020 http://www.ptanatto.gpv.br/cctvn pa ' a102019=202212Q20{decretoJOl 0543.htm.

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• A autenllcldade desLedocumento pode ser conferlda **no** site st" J .iill:-https:llsel anvisa gov br/eutenUcidade. In ormando o c6dlgo verificaclor **1834317** e o codlgo **CRC 34CA332F**.

MINISTRY OF HEALTH

NATIONAL HEALTH SURVEILLANCE AGENCY

GOOD MANUFACTURING PRACTICES FOR DRUGS CERTIFICATION
ACTIVE PHARMACEUTICAL DRUGS

L NE OF BIOLOGIC ACTIVE PHARMACEUTICAL INGREDIENTS

The NatJonal Health Surveillance Agency - **ANVISA**, by means of Resolution RE no. 1.036, of 31/0_3/2Q22, publlshed in the Official Federal Gazette (DOU} on 04/04/2022, hereby certifies that the company named below is periodically inspected and monitored by the National Health Surveillance System and that it complies with lhe Good Manufacturing Practice guidelines laid down by Brazilian legislation, which Is In llne wlth the recommendations of the World Health Organization.

Company: Institute Butantan CNPJ: 61.821.34410001·66
Address: Avenida Vital Brasil N° 1500, Butanta (predlo 41)
Municipality: Sao Paulo UF: SP
F'le(s): 3911692/21-8
Good Manufacturing Practice Certificate for Active Pharmaceutical Ingredients:
Biological active pharmaceutical Ingredients: het.erologous immunoglobulins.

This certification s valid until 04/04/2024 **and may** be withdrawn if it is proven, by the competent health authority, that the requirements of the current Good Practioes regulatlons have not been met.

Document digitally signe-d by Ana carolina Moreira Mar1no Araujo, General M.anager of Publi,c Health Inspectlon and Surveillance, on 04104/2022, at 10:36 as per Bra.sflla official local time, pursuant to article 4, subparagraph 3, of Deeree n.10.543, r;if 13 NQvomber 2020 http:f/www.planalto.gov.br/cc_vii_03/_ato2019-_202212020fdecr&to/D10543.h_m.

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The authenticity of this document can be verified at https://sei.anvisa.gov.br/_utentlcld_de, by entering the verification code B34317 and the CRC code J4CA332F.

Global Connects
we love languages

C RT IC TE OF TRA SLATIO

Project No: 2022 / 63

Global Connections (Scotland) Ltd hereby certifies that this translation was carried out by a competent translator in the languages involved and that it is true and accurate to the photocopied source document attached herewith and

Signed [redacted] Date: 12/07/22

Global Connections (Scotland) Ltd 3rd Floor, 180 Hope Street, Glasgow G2 2UE
Tel: 0141 332 8889 Fax: 0141 332 6681 Email: info@globalconnects.com

ANNEX B - Certificate of Analysis

INSTITUTO BUTANTAN A serviço da vida	STATE HEALTH DEPARTMENT BUTANTANINSTITUTE
	CERTIFICATE OF ANALYSIS
PRODUCT:	di hth&rla anUtox1n 1000 IU/ml
BATCH:	220188
DOCUMENT DATE:	07101'2022

[redacted]

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STATE HEALTH DEPARTMENT
BUTANTAN INSTITUTE

CERTIFICATE OF ANALYSIS

PRODUCT:	di htherla anUtoxln 1000 IU/ml
BATCH:	**220188**
DOCUMENT DATE:	**07/01'2022**

[redacted]

INSTITIJTO !	STATE HEALTH DEPARTMENT BUTANTANINSTITUTE	a
	CERTIFICATE OF ANALYSIS	
PRODUCT:	I diphtheria antitoxin 1000 IU/mL	
BATCH:	I 220188	
DOCUMENT DATE:	I D7/0112022	

[redacted]

I>r INSTITU 0 £!	STATE HEALTH DEPARTMENT **8UTANTAN** INSTITUTE CERTIFICATE OF **ANALYSIS**	a
PRODUCT:	I **di11hlheria** antitoxin 1000 IU/ml	
BATCH:	**220188**	
DOCUMENT DATE:	07/0112DZ2	

[redacted]

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INSTITUTO BUTANTAN
A serviço da vida

STATE HEALTH DEPARTMENT
BUTANTAN INSTITUTE

CERTtFICATE OF ANALYSIS

PRODUCT: BULK ANTIDIPHTHERAL SERUM 1000 IUlmL
BATCH: SDIF1022-0001
DOCUMENT DATE: 07/01/"2022

Production Records

[redacted]

[redacted]

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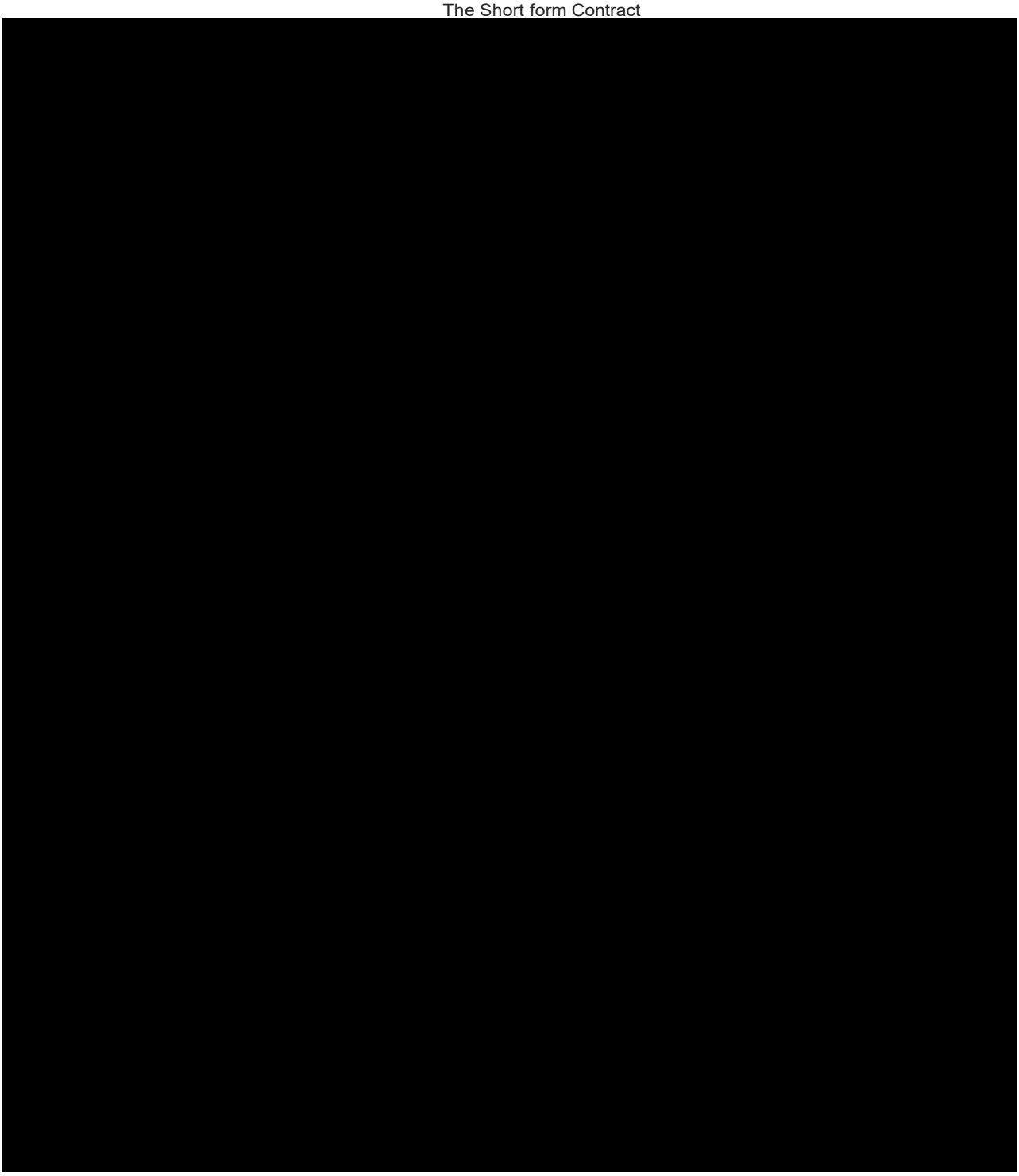

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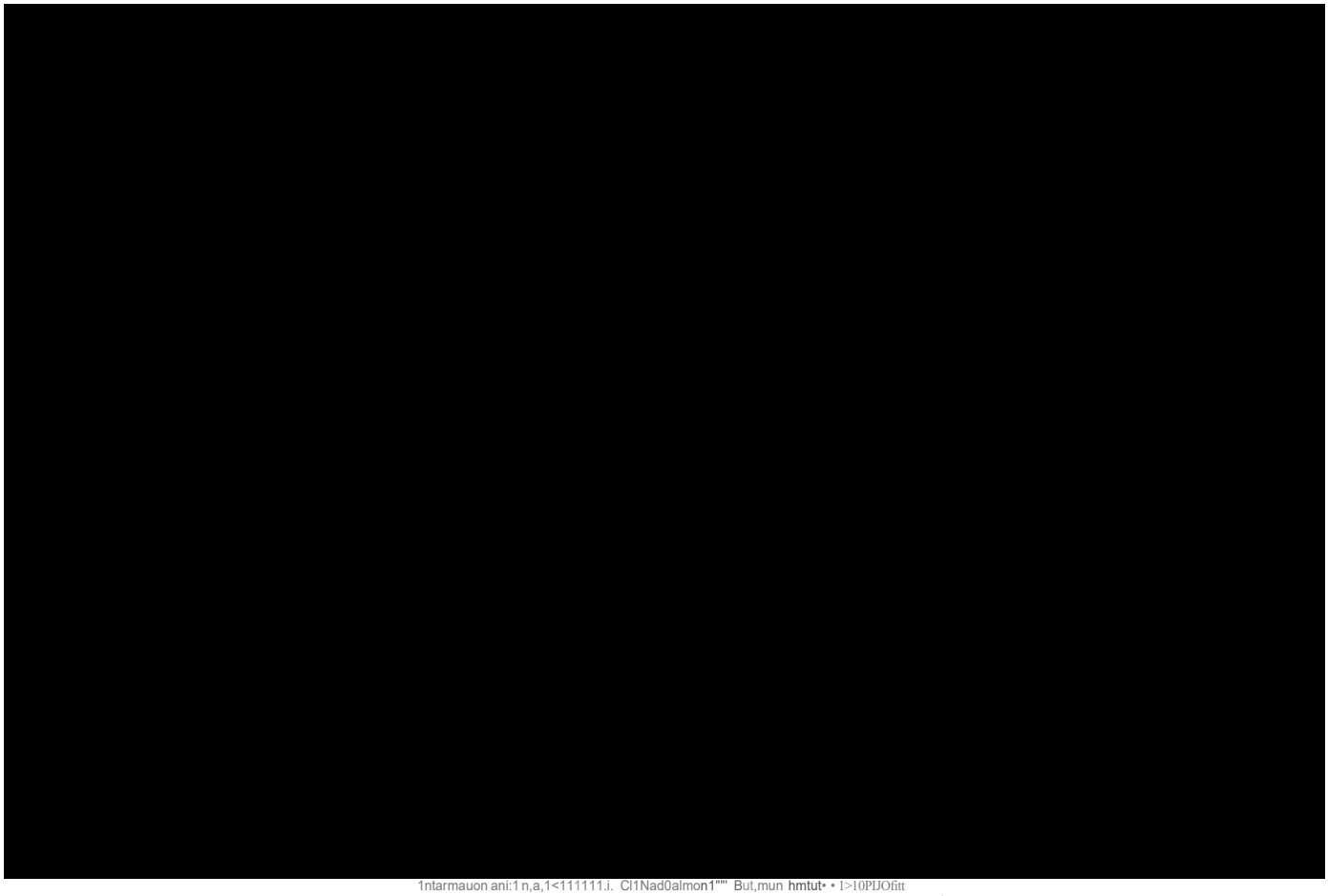

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The Short form Contract

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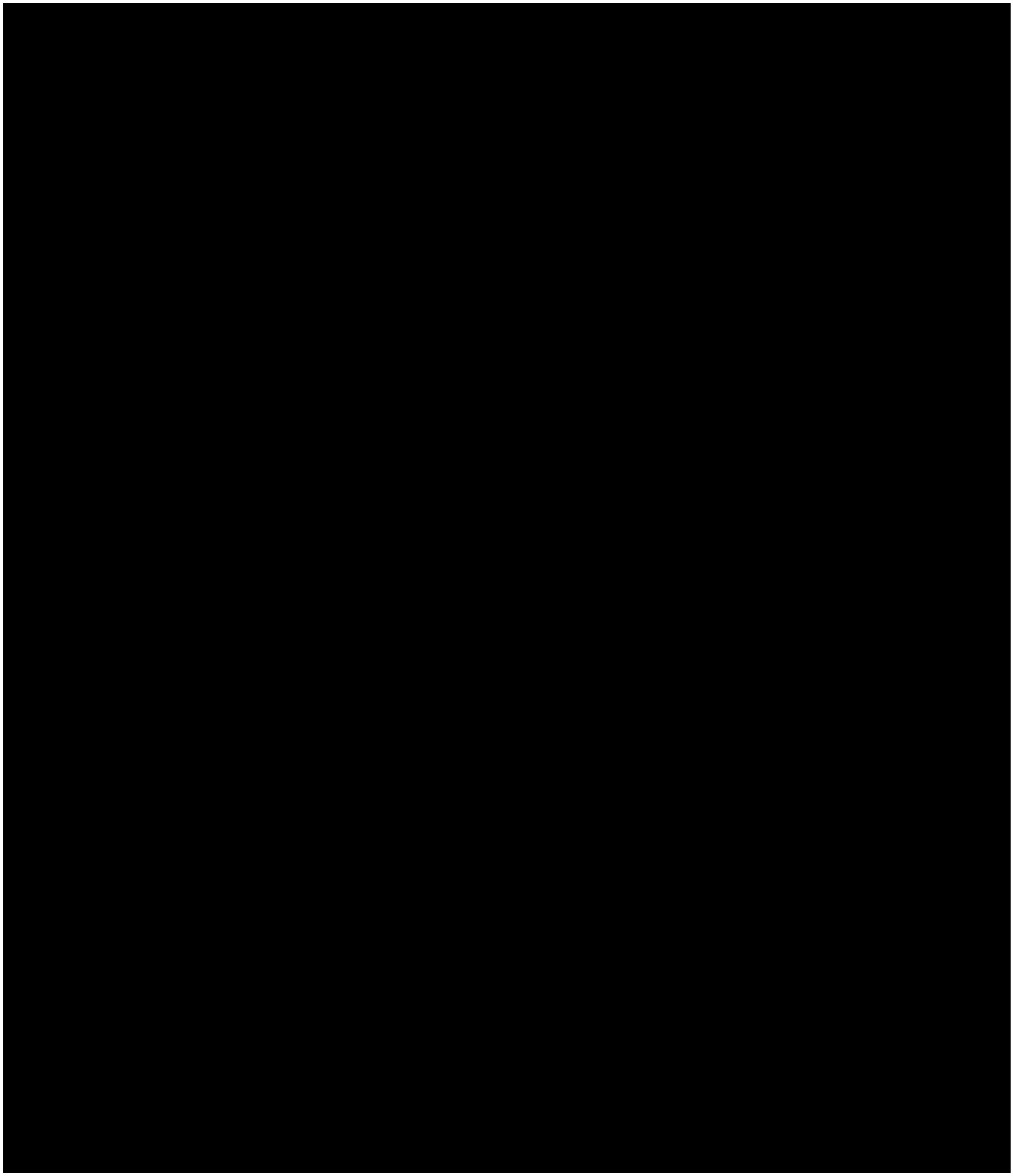
ANNEX C - Lot Release Certificate



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ANNEX D • Patient Information Leaflet

INSTITUTO BUTANTAN

Diphtheria Antitoxin (DAT)
[illegible] IU/mL equine-derived immunoglobulin against the diphtheria toxin

GOVERNO DO ESTADO DE SÃO PAULO

DOSAGE FORM
Injectable solution

Each mL of DAT neutralises at least [illegible] of diphtheria toxin out of at least a total of a 10.000 IU in a 10 mL vial.

Each carton contains 5 vials with 10 mL of diphtheria antitoxin.

Diphtheria antitoxin is supplied in 10 mL vial containing an injectable solution of the specific and purified F(ab')₂ equine-derived immunoglobulin fractions. Each vial neutralises at least 10.000 IU of toxin produced by *Corynebacterium diphtheriae* (serum neutralization in guinea pigs).

Diphtheria antitoxin is produced from the plasma of horses hyperimmunized with diphtheria anatoxin.

ROUTE OF ADMINISTRATION: INTRAVENOUS.

ADULT AND PEDIATRIC USE.

COMPOSITION 1.000 IU/mL
Each 10 mL vial contains:
- F(ab')₂ equine-derived immunoglobulin fractions neutralizing at least 10,000 IU of the diphtheria toxin (serum neutralization in guinea pigs);
- phenol .... 35 mg (maximum);
- saline solution at 0.85% .... q.s. 10 mL.

1. INDICATIONS
This product is indicated for the treatment of patients with diphtheria. Diphtheria antitoxin is the only effective drug product that neutralises the toxin secreted by the diphtheria bacillus (*Corynebacterium diphtheriae*). The antibodies (specific immunoglobulins) contained in the antitoxin bind to the toxin that is not yet fixed to the tissues and neutralise it. In these conditions, the earlier the administration of the antitoxin, the better the therapeutic response; therefore, treatment must be started as soon as possible.

2. EFFICACY RESULTS
There are no controlled clinical trials assessing the efficacy of DAT originating from horse plasma, however, its capacity to neutralize the toxic activities of the toxins has been demonstrated in laboratory animal models and in the systematic use in patients.

3. PHARMACOLOGICAL CHARACTERISTICS
Diphtheria antitoxin is an isotonic solution of equine-derived specific immunoglobulins (IgG), purified by enzymatic, non-pyrogenic digestion. The immunoglobulins derive from the plasma of healthy horses, hyperimmunized with diphtheria anatoxin. The neutralizing biological activity of the antitoxin against the diphtheria toxin is assessed by the protection obtained in guinea pigs, after subcutaneous inoculation of mixtures of different volumes of antitoxin with a fixed amount of the reference diphtheria toxin. The neutralizing power of DAT should be of at least 1,000 International Units (IU) per mL of product.
Equine plasma enzymatically digested by pepsin reduces IgG molecular weight from 160 kDa to 90 kDa or 100 kDa, eliminating the Fc fraction from the immunoglobulin molecule that is responsible for the activation of the classical complement pathway. Thus, a molecule less reactive regarding hypersensitivity events observed in patients is obtained. The neutralizing activity of the antigen-binding site of pepsin-treated immunoglobulin molecules remains unchanged and there is a significant reduction in the probability of spontaneous formation of protein aggregates, which is also responsible for undesirable allergic reactions. Despite the highly purified degree of the antitoxin, there is still a small potential for allergic reactions in hypersensitive individuals. Among the undesirable reactions, anaphylaxis can occur by mast cell degranulation or complement system activation, although lethal anaphylactic shock is very rare.
Once attached to the tissues, the diphtheria toxin is not neutralized by DAT.
Diphtheria antitoxin neutralizes circulating diphtheria toxin but does not eliminate *C. diphtheriae* from the bloodstream.

4. CONTRAINDICATIONS
There are practically no contraindications but in patients with an allergic history or sensitivity to equine-derived immunoglobulins, DAT should be administered alongside strict medical observation.

NOTES:
- Diphtheria antitoxin is not contraindicated in pregnancy but the physician should be informed about this condition;
- Prior feeding and/or drinking do not contraindicate the use of the DAT, but greater care is required due to the risk of vomiting aspiration.

5. WARNINGS AND PRECAUTIONS FOR USE

Diphtheria antitoxin must be administered intravenously and under medical supervision.

Store DAT refrigerated between +2°C and +8°C. DO NOT FREEZE.

Once opened, the DAT vial must be used immediately.

NOTES:
- Success of diphtheria treatment with DAT is directly related to the ear[illegible] possible administration of the correct doses after [illegible] start of symptoms thus requiring [illegible]

[illegible] or sensitivity to equine-derived immunoglobulins are considered risk groups;
- Treatment discontinuation should only occur if recommended by a physician.

4. DRUG INTERACTIONS
No concomitant medication is contraindicated to be administered with DAT but physicians should be informed about any medications used by patients.

[illegible]
Diphtheria antitoxin should be stored and [illegible] between +2°C and +8°C. Do not store in [illegible] freezing is strictly contraindicated. Once [illegible] drug must be used immediately.

SHELF-LIFE:
Shelf life of DAT is of 36 months from date of manufacture provided it has been stored refrigerated between +2°C and +8°C as indicated on the package. These instructions have to be strictly followed.

Batch number and date of manufacture and date of expiry: see packaging.

Do not take this medic[illegible]
Store in original packag[illegible]

[illegible] product [illegible] which is colorless to [illegible] turbidity or precipitates at [illegible]

Inspect the appearance [illegible] using it.

Store medicines out of the [illegible] children.

8. DOSAGE AND ADMINISTRATION
Diphtheria antitoxin should be administered intravenously, in a single application, under medical supervision and at the doses prescribed according to clinical form or severity:

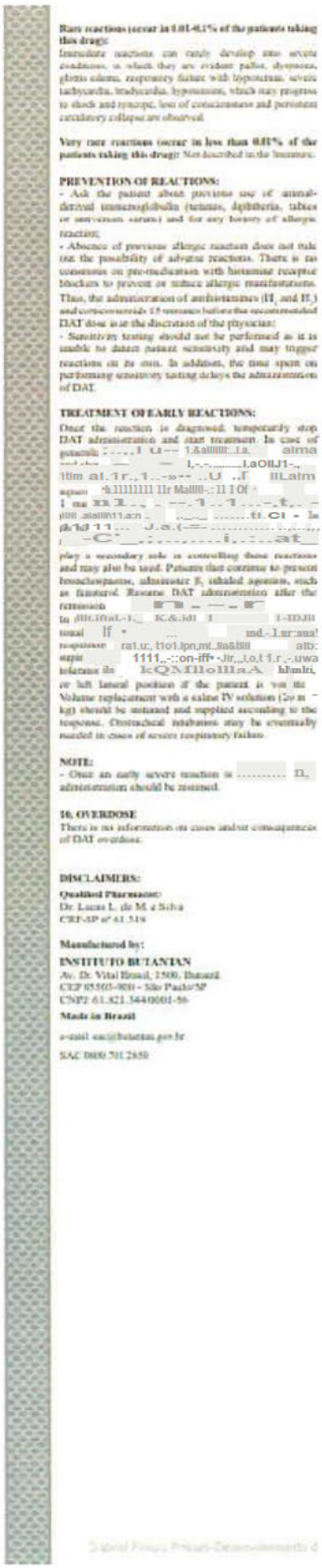
MILD FORM (nose, skin, tonsils): 40,000 IU
MODERATE FORM (larynx, tonsils or mixed): [illegible] to 80,000 IU
SEVERE OR LATE FORM (4 days after disease [illegible] 80,000 to 100,000 IU
Administer DAT by slow intravenous infusio[illegible] antitoxin dose should be diluted in 100 mL of [illegible] saline solution or as required. Note, however, for the risk of volume overload in children and patients with heart failure. Doses of DAT should not be fractionated. The frequency of reactions to DAT appears to be lower when the diluted product is administered.

SPECIAL RECOMMENDATIONS:
- Diphtheria antitoxin is effective only for the treatment of diphtheria;
- Antibiotic therapy should also be introduced and administered to eliminate *C. diphtheriae* and thereby interrupt the production of diphtheria toxin;
- Treatment discontinuation should only occur if recommended by a physician.
- Administer the same dose of DAT for the treatment of diphtheria in adults and children.

9. ADVERSE REACTIONS
Very common reactions (occur in 10% of patients taking this drug):
Immediate and early reactions may occur during the infusion and for two hours thereafter, and up to 24 hours after administration of the DAT. They are often mild reactions. In addition to releasing histamine, animal-derived proteins can lead to the formation of protein or immunocomplex aggregates that activate the complement system. This, in turn, can lead to the formation of anaphylatoxins and trigger the release of mast cell and basophil chemical mediators. The most common signs and symptoms are pruritus, urticaria, facial flushing, angioedema, [illegible] tachycardia, rhinorrhea, sneezing, coughing, nausea, abdominal cramps and diarrhea.

Common reactions (occur in 1-10% of patients taking this drug):
Late reaction, also known as Serum Sickness, can occur 5 to 24 days after the use of animal-derived immunoglobulins. The reaction is initially characterized by fever, urticaria, rashes of different size and irregularly distributed. Joint involvement can occur, at times severe and usually involving large joints, presenting with swelling with no redness, spontaneous and pressure-related pain and difficulty in motion. Lymph node infection produces generalized adenopathy of different intensity, resulting in palpable, mobile and painful nodes. The symptoms usually disappear with no sequelae. Vasculitis and nephritis rarely occur.

Uncommon reactions (occur in 0.1-1% of the patients [illegible] this drug):
[illegible] reaction, described [illegible] decreasing frequency [illegible] during the use of the [illegible] and can lead to [illegible] perature (up to 39°C) [illegible] panied by chills and [illegible] In such cases, the in[illegible] should be discontinued [illegible] After symptoms [illegible] started. If symptoms [illegible] prepare a new [illegible]



Rare reactions (occur in 0.01-0.1% of the patients taking this drug):
Immediate reactions can rarely develop into severe conditions, in which they are evident pallor, dyspnoea, glottis edema, respiratory failure with hypoxemia, severe tachycardia, bradycardia, hypotension, which may progress to shock and syncope, loss of consciousness and persistent circulatory collapse are observed.

Very rare reactions (occur in less than 0.01% of the patients taking this drug): Not described in the literature.

PREVENTION OF REACTIONS:
- Ask the patient about previous use of animal-derived immunoglobulin (tetanus, diphtheria, rabies or antivenom serum) and for any history of allergic reactions;
- Absence of previous allergic reaction does not rule out the possibility of adverse reactions. There is no consensus on pre-medication with histamine receptor blockers to prevent or reduce allergic manifestations. Thus, the administration of antihistamines (H_1 and H_2) and corticosteroids 15 minutes before the recommended DAT dose is at the discretion of the physician;
- Sensitivity testing should not be performed as it is unable to detect patient sensitivity and may trigger reactions on its own. In addition, the time spent on performing sensitivity testing delays the administration of DAT.

TREATMENT OF EARLY REACTIONS:
Once the reaction is diagnosed, temporarily stop DAT administration and start treatment. In case of patients [illegible] play a secondary role in controlling these reactions and may also be used. Patients that continue to present bronchospasm, administer β_2 inhaled agonists, such as fenoterol. Resume DAT administration after the remission [illegible] total [illegible] respiratory [illegible] tolerance [illegible] or left lateral position if the patient is vomiting. Volume replacement with a saline IV solution (20 ml kg) should be initiated and supplied according to the response. Orotracheal intubation may be eventually needed in cases of severe respiratory failure.

NOTE:
- Once an early severe reaction is [illegible] administration should be resumed.

10. OVERDOSE
There is no information on cases and/or consequences of DAT overdose.

DISCLAIMERS:

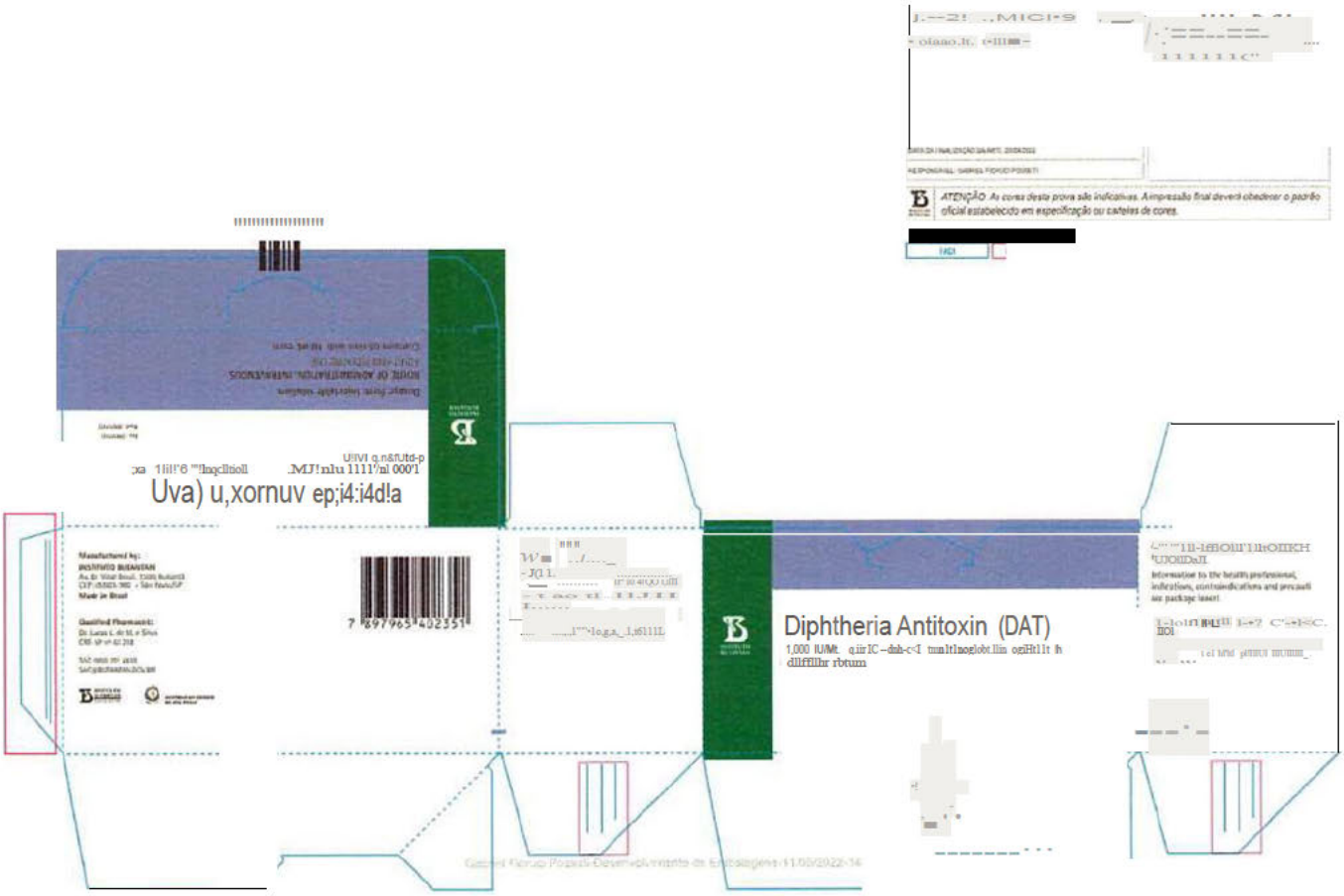
Qualified Pharmacist:
Dr. Lucas L. de M. e Silva
CRF-SP nº 61.519

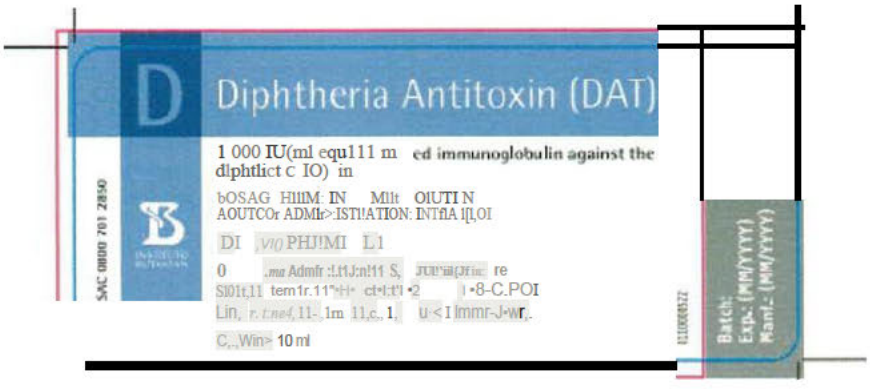
Manufactured by:
INSTITUTO BUTANTAN
Av. Dr. Vital Brasil, 1500, Butantã
CEP 05503-900 - São Paulo/SP
CNPJ 61.821.544/0001-50
Made in Brazil

e-mail: sac@butantan.gov.br

SAC 0800 701 2650

ANNEX E - Packaging





200% do tamanho real

ANNEX F - Transmissible Spongiform Encephalopathy Statement

funda ao
butantan

TSE Statement

Date : 6 July, 2022

Shipper:

Funda o Butantan
Avenida Vital Brasil. 1500- Cep 05503-900
Butantan - Silo Paulo - SP
Caio Franzoso - Phone 55 11 2627-3742

Consign e:

[redacted]

[redacted]ctious **agen** . The m nufacturlng process not Inciude any raw material of bovine origin Product Intend d for human use only.

The O phtheda Antitoxin will be used in patlents to help minimize the effect of Dlphtherla **di eas** .

Cordially,

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No r9t N godos
F lipe A. Carvilh
Business Developm nt Speclil 1st
Funda o Butanta

Fundação Butantan
Rua Alvarenga, 1396
Butantã, São Paulo/SP
CEP: 05509-002

www.fundacaobutantan.org.br

APPENDIX 1- Short Form Terms and Conditions

Short form Terms

1. Definitions used in the Contract

In this Contract, unless the context otherwise requires, the following words shall have the following meanings:

"Central Government Body"	means a body listed in one of the following sub- categories of the Central Government classification of the Public Sector Classification Guide, as published andamended from time to time by the Office for National Statistics: a) Government Department; b) Non-Departmental Public Body or Assembly Sponsored Public Body (advisory, executive, or tribunal); c) Non-Ministerial Department; or d) Executive Agency;
"Charges"	means the charges for the Deliverables as specified in the Order Form;
"Confidential Information"	means all information, whether written or oral (however recorded), provided by the disclosing Party to the receiving Party and which (i) is known by the receiving Party to be confidential; (ii) is marked as or stated to be confidential; or (iii) ought reasonably to be considered by the receiving Party to be confidential;
"Contract"	means the contract between (i) the Buyer and (ii) the Supplier which is created by the Supplier's counter signing the Order Form and includes the Order Form and Annexes;
"Controller"	has the meaning given to it in the GDPR;
"Buyer"	means the person identified in the letterhead of the Order Form;
"Date of Delivery"	means that date by which the Deliverables must be delivered to the Buyer, as specified in the Order Form;
"Buyer Cause"	any breach of the obligations of the Buyer or any other default, act, omission, negligence or statement of the Buyer, of its employees, servants, agents in connection with or in relation to the subject-matter of the Contract and in respect of which the Buyer is liable to the Supplier;
"Data Protection Legislation"	(i) the GDPR, the LED and any applicable national implementing Laws as amended from time to time (ii) the Data Protection Act 2018 to the extent that it relates to processing

	of personal data and privacy; (iii) all applicable Law about the processing of personal data and privacy;
"Data Protection Impact Assessment"	an assessment by the Controller of the impact of the envisaged processing on the protection of Personal Data;
"Data Pro-tectionOf-ficer"	has the meaning given to it in the GDPR;
"Data Subject"	has the meaning given to it in the GDPR;
"Data Loss Event"	any event that results, or may result, in unauthorised access to Personal Data held by the Supplier under this Contract, and/or actual or potential loss and/or destruction of Personal Data in breach of this Contract, including any Personal Data Breach;
"Data Subject Access Request"	a request made by, or on behalf of, a Data Subject in accordance with rights granted pursuant to the Data Protection Legislation to access their Personal Data;
"Deliver"	means hand over the Deliverables to the Buyer at the address and on the date specified in the Order Form, which shallinclude unloading and any other specific arrangements agreedin accordance with Clause [ ]. Delivered and Delivery shall be construed accordingly;
"Existing IPR"	any and all intellectual property rights that are owned by or licensed to either Party and which have been developed independently of the Contract (whether prior to the date of theContract or otherwise);
"Expiry Date"	means the date for expiry of the Contract as set out in the Order Form;
"FOIA"	means the Freedom of Information Act 2000 together with any guidance and/or codes of practice issued by the Information Commissioner or relevant Government department in relation to such legislation;
"Force Majeure Event"	any event, occurrence, circumstance, matter or cause affecting the performance by either Party of its obligations under the Contract arising from acts, events, omissions, happenings or non-happenings beyond its reasonable control which prevent or materially delay it from performing its obligations under the Contract but excluding: i) any industrial dispute relating to the Supplier, the Supplier Staff (including any subsets of them) or any other failure in the Supplier or the Subcontractor's supply chain; ii) any event, occurrence, circumstance, matter or cause which is attributable to the wilful act, neglect or failure to take reasonable precautions against it by the Party concerned; and iii) any failure of delay caused by a lack of funds;

"GDPR"	the General Data Protection Regulation (Regulation (EU) 2016/679);
"Goods"	means the goods to be supplied by the Supplier to the Buyer under the Contract;
"Good Industry Practice"	standards, practices, methods and procedures conforming to the law and the exercise of the degree of skill and care, diligence, prudence and foresight which would reasonably andordinarily be expected from a skilled and experienced person or body engaged within the relevant industry or business sector;
"Government Data"	a) the data, **text,** drawings, diagrams, images or sounds (together with any database made up of any of these) which are embodied in any electronic, magnetic, optical or tangible media, including any of the Buyer's confidential information, and which: i) are supplied to the Supplier by or on behalf ofthe Buyer; or ii) the Supplier is required to generate, process, store or transmit pursuant to the Contract; or b) any Personal Data for which the Buyer is the Data Controller;
"Information"	has the meaning given under section 84 of the FOIA;
"Information Commissioner"	the UK's independent authority which deals with ensuring information relating to rights in the public interest and data privacy for individuals is met, whilst promoting openness by public bodies;
"Insolvency Event"	in respect of a person: a) if that person is insolvent; ii) if an order is made or a resolution is passed for the winding up of the person (other than voluntarily for the purpose of solvent amalgamation or reconstruction); iii) if an administrator or administrative receiver is appointed in respect of the whole or any part of the persons assets or business; iv) if the person makes any composition with its creditors or takes or suffers any similar or analogous action to any of the actions detailed in this definition as a result of debt in any jurisdiction;
"Key Personnel"	means any persons specified as such in the Order Form or otherwise notified as such by the Buyer to the Supplier in writing;
"LED"	Law Enforcement Directive (Directive (EU) 2016/680);
"New IPR"	all and intellectual property rights in any materials created or developed by or on behalf of the Supplier pursuant to the Contract but shall not include the Supplier's Existing IPR;
"Order Form"	means the letter from the Buyer to the Supplier printed above these terms and conditions;
"Party"	the Supplier or the Buyer (as appropriate) and "Parties" shall mean both of them;
"Personal Data"	has the meaning given to it in the GDPR;

"Personal Data Breach"	has the meaning given to it in the GDPR;
"Processor"	has the meaning given to it in the GDPR;
"Purchase Order Number"	means the Buyer's unique number relating to the order for Deliverables to be supplied by the Supplier to the Buyer in accordance with the terms of the Cor:1tract;
"Regulations"	the Public Contracts Regulations 2015 and/or the PublicContracts (Scotland) Regulations 2015 (as the context requires) as amended from time to time;
"Request for Information"	has the meaning set out in the FOIA or the Environmental Information Regulations 2004 as relevant (where the meaning set out for the term "request" shall apply);
"Services"	means the services to be supplied by the Supplier to the Buyer under the Contract;
"Specification"	means the specification for the Deliverables to be supplied by the Supplier to the Buyer (including as to quantity, description and quality) as specified in the Order Form;
"Staff'	means all directors, officers, employees, agents, consultants and contractors of the Supplier and/or of any sub-contractor of the Supplier engaged in the performance of the Supplier's obligations under the Contract;
"Staff Vetting Procedures"	means vetting procedures that accord with good industry practice or, where applicable, the Buyer's procedures for the vetting of personnel as provided to the Supplier from time to time;
"Subprocessor"	any third Party appointed to process Personal Data on behalf of the Supplier related to the Contract;
"Supplier Staff'	all directors, officers, employees, agents, consultants and contractors of the Supplier and/or of any Subcontractor engaged in the performance of the Supplier's obligations under a Contract;
"Supplier"	means the person named as Supplier in the Order Form;
"Term"	means the period from the start date of the Contract set out in the Order Form to the Expiry Date as such period may be extended in accordance with clause 11.2 or terminated in accordance with the terms and conditions of the Contract;
"US-EU Privacy Shield Register"	a list of companies maintained by the United States of America Department for Commence that have self-certified their commitment to adhere to the European legislation relating to the processing of personal data to non-EU countries which is available online at:https://www.privacyshield.gov/list;

"VAT"	means value added tax in accordance with the provisions of the Value Added Tax Act 1994;
"Workers"	any one of the Supplier Staff which the Buyer, in itsreasonable opinion, considers is an individual to whichProcurement Policy Note 08/15 (Tax Arrangements of PublicAppointees) (https://www.gov.uk/government/publications/procurement- policynote-0815-tax-arrangements-of-appointees) applies in respect of the Deliverables;
"Working Day"	means a day (other than a Saturday or Sunday) on which banks are open for business in the City of London.

2. Understanding the Contract

In the Contract, unless the context otherwise requires:

2.1 references to numbered clauses are references to the relevant clause in these termsand conditions;

2.2 any obligation on any Party not to do or omit to do anything shall include anobligation not to allow that thing to be done or omitted to be done;

2.3 the headings in this Contract are for information only and do not affect theinterpretation of the Contract;

2.4 references to "writing" include printing, display on a screen and electronic transmission and other modes of representing or reproducing words in a visible form;

2.5 the singular includes the plural and vice versa;

2.6 a reference to any law includes a reference to that law as amended, extended, consolidated or re-enacted from time to time and to any legislation or byelaw madeunder that law; and

2.7 the word 'including', "for example" and similar words shall be understood as iftheywere immediately followed by the words "without limitation".

3. How the Contract works

3.1 The Order Form is an offer by the Buyer to purchase the Deliverables subject to andin accordance with the terms and conditions of the Contract.

3.2 The Supplier is deemed to accept the offer in the Order Form when the Buyerreceives a copy of the Order Form signed by the Supplier.

3.3 The Supplier warrants and represents that its tender and all statements made and documents submitted as part of the procurement of Deliverables are and remain trueand accurate.

4. What needs to be delivered

4.1 All Deliverables

(a) The Supplier must provide Deliverables: (i) in accordance with the Specification; (ii) to a professional standard; (iii) using reasonable skill and care; (iv) using Good Industry Practice; (v) using its own policies, processesand internal quality control measures as long as they don't conflict with the Contract; (vi) on the dates agreed; and (vii) that comply with all law.

(b) The Supplier must provide Deliverables with a warranty of at least 90 days (orlonger where the Supplier offers a longer warranty period to its Buyers) from Delivery against all obvious defects.

4.2 Goods clauses

(a) All Goods delivered must be new, or as new if recycled, unused and of recentorigin.

(b) All manufacturer warranties covering the Goods must be assignable to the Buyer on request and for free.

(c) The Supplier transfers ownership of the Goods on completion of delivery (including off-loading and stacking) or payment for those Goods, whichever isearlier.

(d) Risk in the Goods transfers to the Buyer on delivery, but remains with the Supplier if the Buyer notices damage following delivery and lets the Supplierknow within three Working Days of delivery.

(e) The Supplier warrants that it has full and unrestricted ownership of the Goods at the time of transfer of ownership.

(f) The Supplier must deliver the Goods on the date and to the specified location during the Buyer's working hours.

(g) The Supplier must provide sufficient packaging for the Goods to reach the pointof delivery safely and undamaged.

(h) All deliveries must have a delivery note attached that specifies the ordernumber, type and quantity of Goods.

(i) The Supplier must provide all tools, information and instructions the Buyer needs to make use of the Goods.

U) The Supplier will notify the Buyer of any request that Goods are returned to it or the manufacturer after the discovery of safety issues or defects that might endanger health or hinder performance and shall indemnify the Buyer against the costs arising as a result of any such request.

(k) The Buyer can cancel any order or part order of Goods which has not been delivered. If the Buyer gives less than 14 days' notice then it will pay the Supplier's reasonable and proven costs already incurred on the cancelled orderas long as the Supplier takes all reasonable steps to minimise these costs.

(l) The Supplier must at its own cost repair, replace, refund or substitute (at the Buyer's option and request) any Goods that the Buyer rejects because they don't conform with clause **4.2. If** the Supplier doesn't do this it will pay the Buyer's costs including repair or re-supply by a third party.

(m) The Buyer will not be liable for any actions, claims, costs and expenses incurred by the Supplier or any third party during delivery of the Goods unlessand to the extent that it is caused by negligence or other wrongful act of the Buyer or its servant or agent. If the Buyer suffers or incurs any damage or injury (whether fatal or otherwise) occurring in the course of delivery or

installation then the Supplier shall indemnify from any losses, charges costs or expenses which arise as a result of or in connection with such damage or injury where it is attributable to any act or omission of the Supplier or any of its [sub-suppliers].

4.3 Services clauses

(a) Late delivery of the Services will be a default of the Contract.

(b) The Supplier must co-operate with the Buyer and third party suppliers on all aspects connected with the delivery of the Services and ensure that SupplierStaff comply with any reasonable instructions including any security requirements.

(c) The Buyer must provide the Supplier with reasonable access to its premises atreasonable times for the purpose of supplying the Services

(d) The Supplier must at its own risk and expense provide all equipment required to deliver the Services. Any equipment provided by the Buyer to the Supplier for supplying the Services remains the property of the Buyer and is to be returned to the Buyer on expiry or termination of the Contract.

(e) The Supplier must allocate sufficient resources and appropriate expertise to theContract.

(f) The Supplier must take all reasonable care to ensure performance does notdisrupt the Buyer's operations, employees or other contractors.

(g) On completion of the Services, the Supplier is responsible for leaving the Buyer's premises in a clean, safe and tidy condition and making good any damage that it has caused to the Buyer's premises or property, other than fairwear and tear.

(h) The Supplier must ensure all Services, and anything used to deliver theServices, are of good quality and free from defects.

(i) The Buyer is entitled to withhold payment for partially or undelivered Services,but doing so does not stop it from using its other rights under the Contract.

5. Pricing and payments

5.1 In exchange for the Deliverables, the Supplier shall be entitled to invoice the Buyer for the charges in the Order Form. The Supplier shall raise invoices promptly and inany event within 90 days from when the charges are due.

5.2 All Charges:

(a) exclude VAT, which is payable on provision of a valid VAT invoice;

(b) include all costs connected with the supply of Deliverables.

5.3 The Buyer must pay the Supplier the charges within 30 days of receipt by the Buyer of a valid, undisputed invoice, in cleared funds to the Supplier's account stated in theOrder Form.

5.4 A Supplier invoice is only valid if it:

(a) includes all appropriate references including the Purchase Order Number andother details reasonably requested by the Buyer;

(b) includes a detailed breakdown of Deliverables which have been delivered (ifany).

5.5 If there is a dispute between the Parties as to the amount invoiced, the Buyer shallpay the undisputed amount. The Supplier shall not suspend the provision of the Deliverables unless the Supplier is entitled to terminate the Contract for a failure topay undisputed sums in accordance with clause 11.6. Any disputed amounts shallbe resolved through the dispute resolution procedure detailed in clause 33.

5.6 The Buyer may retain or set-off payment of any amount owed to it by the Supplier ifnotice and reasons are provided.

5.7 The Supplier must ensure that all subcontractors are paid, in full, within 30 days of receipt of a valid, undisputed invoice. If this doesn't happen, the Buyer can publishthe details of the late payment or non-payment.

6. The Buyer's obligations to the Supplier

6.1 If Supplier fails to comply with the Contract as a result of a Buyer Cause:

(a) the Buyer cannot terminate the Contract under clause 11;
(b) the Supplier is entitled to reasonable and proven additional expenses and torelief from liability under this Contract;
(c) the Supplier is entitled to additional time needed to deliver the Deliverables;
(d) the Supplier cannot suspend the ongoing supply of Deliverables.

6.2 Clause 6.1 only applies if the Supplier:

(a) gives notice to the Buyer within 10 Working Days of becoming aware;
(b) demonstrates that the failure only happened because of the Buyer Cause;
(c) mitigated the impact of the Buyer Cause.

7. Record keeping and reporting

7.1 The Supplier must ensure that suitably qualified representatives attend progress meetings with the Buyer and provide progress reports when specified in the OrderForm.

7.2 The Supplier must keep and maintain full and accurate records and accounts oneverything to do with the Contract for seven years after the date of expiry or termination of the Contract.

7.3 The Supplier must allow any auditor appointed by the Buyer access to their premisesto verify all contract accounts and records of everything to do with the Contract and provide copies for the audit.

7.4 The Supplier must provide information to the auditor and reasonable co-operation attheir request.

7.5 If the Supplier is not providing any of the Deliverables, or is unable to provide them, itmust immediately:

(a) tell the Buyer and give reasons;
(b) propose corrective action;

(c) provide a deadline for completing the corrective action.

7.6 If the Buyer, acting reasonably, is concerned as to the financial stability of the Supplier such that it may impact on the continued performance of the Contract thenthe Buyer may:

(a) require that the Supplier provide to the Buyer (for its approval) a plan setting out how the Supplier will ensure continued performance of the Contract and theSupplier will make changes to such plan as reasonably required by the Buyer and once it is agreed then the Supplier shall act in accordance with such plan and report to the Buyer on demand

(b) if the Supplier fails to provide a plan or fails to agree any changes which arerequested by the Buyer or fails to implement or provide updates on progresswith the plan, terminate the Contract immediately for material breach (or on such date as the Buyer notifies).

8. Supplier staff

8.1 The Supplier Staff involved in the performance of the Contract must:

(a) be appropriately trained and qualified;

(b) be vetted using Good Industry Practice and in accordance with the instructions issued by the Buyer in the Order Form] [Staff Vetting Procedures];

(c) comply with all conduct requirements when on the Buyer's premises.

8.2 Where a Buyer decides one of the Supplier's Staff isn't suitable to work on theContract, the Supplier must replace them with a suitably qualified alternative.

8.3 If requested, the Supplier must replace any person whose acts or omissions havecaused the Supplier to breach clause 8.

8.4 The Supplier must provide a list of Supplier Staff needing to access the Buyer'spremises and say why access is required.

8.5 The Supplier indemnifies the Buyer against all claims brought by any person employed by the Supplier caused by an act or omission of the Supplier or anySupplier Staff.

8.6 The Supplier shall use those persons nominated in the Order Form (if any) to providethe Deliverables and shall not remove or replace any of them unless:

(a) requested to do so by the Buyer (not to be unreasonably withheld or delayed);

(b) the person concerned resigns, retires or dies or is on maternity or long-termsick leave; or

(c) the person's employment or contractual arrangement with the Supplier or anysubcontractor is terminated for material breach of contract by the employee.

9. Rights and protection

9.1 The Supplier warrants and represents that:

(a) it has full capacity and authority to enter into and to perform the Contract;

(b) the Contract is executed by its authorised representative;

(c) it is a legally valid and existing organisation incorporated in the place it was formed;

(d) there are no known legal or regulatory actions or investigations before any court, administrative body or arbitration tribunal pending or threatened against itor its affiliates that might affect its ability to perform the Contract;
(e) it maintains all necessary rights, authorisations, licences and consents toperform its obligations under the Contract;
(f) it doesn't have any contractual obligations which are likely to have a materialadverse effect on its ability to perform the Contract; and
(g) it is not impacted by an Insolvency Event.

9.2 The warranties and representations in clause 9.1 are repeated each time the Supplierprovides Deliverables under the Contract.

9.3 The Supplier indemnifies the Buyer against each of the following:
(a) wilful misconduct of the Supplier, any of its subcontractor and/or Supplier Staffthat impacts the Contract;
(b) non-payment by the Supplier of any tax or National Insurance.

9.4 If the Supplier becomes aware of a representation or warranty that becomes untrueor misleading, it must immediately notify the Buyer.

9.5 All third party warranties and indemnities covering the Deliverables must be assignedfor the Buyer's benefit by the Supplier.

10. Intellectual Property Rights (IPRs)

10.1 Each Party keeps ownership of its own Existing IPRs. The Supplier gives the Buyer a non-exclusive, perpetual, royalty-free, irrevocable, transferable worldwide licence touse, change and sub-license the Supplier's Existing IPR to enable it and its sub- licensees to both:
(a) receive and use the Deliverables;
(b) use the New IPR.

10.2 Any New IPR created under the Contract is owned by the Buyer. The Buyer gives the Supplier a licence to use any Existing IPRs for the purpose of fulfilling its obligations under the Contract and a perpetual, royalty-free, non-exclusive licence touse any New IPRs.

10.3 Where a Party acquires ownership of intellectual property rights incorrectly under thisContract it must do everything reasonably necessary to complete a transfer assigningthem in writing to the other Party on request and at its own cost.

10.4 Neither Party has the right to use the other Party's intellectual property rights,including any use of the other Party's names, logos or trademarks, except asprovided in clause 10 or otherwise agreed in writing.

10.5 If any claim is made against the Buyer for actual or alleged infringement of a third party's intellectual property arising out of, or in connection with, the supply or use of the Deliverables (an **"IPR Claim"),** then the Supplier indemnifies the Buyer against alllosses, damages, costs or expenses (including professional fees and fines) incurred as a result of the IPR Claim.