FUNDAÇÃO BUTANTAN
Gestão é uma ciência

PROCESSO Nº WS2156641074

EDITAL DE COTAÇÃO SIMPLIFICADA N.º 023/2026

OBJETO DA SELEÇÃO: Aquisição em lotes para o prédio 1017 responsável pela produção do Insumo Farmacêutico Ativo (IFA) da vacina dTpa de uma Autoclave de uma descontaminação 1250 litros (sala 1013); uma Autoclave de descontaminação 1250 litros (sala 2008); Autoclave de descontaminação 1250L (sala 1017); uma Autoclave de esterilização 1500L; uma Autoclave de esterilização 726 litros; uma Autoclave de descontaminação de 450 litros; uma lavadora de materiais; e um forno de Forno de despirogenização, sendo os todos equipamentos acompanhados dos serviços de erviços de Pré- FAT, Factory Acceptance Test (FAT), Instalação, Calibrações, Comissionamento, Start-up, Site acceptance test (SAT), Qualificação de instalação (QI), Qualificação de operação (QO), Qualificação de desempenho (QD), Qualificação térmica (QT) e treinamento operacional e de manutenção.

RESPOSTAS ÀS DÚVIDAS N° 02

		DIN-01017-ANX-FD-0001_01_FornoDespirogenizacao_Assinada (17-09-2025)	COMMENTS	Customer Reply / Date
2.0	Reference Documents	Equipment List - DT-01017-PE-PR-LQ-0001_06 - Quantitative Equipment List Layout: DOP-01017-PE-AI-DE-1205_00 (Layout Plan - 2nd floor)	This documents are not shared, so they are not considered at this stage. Please share with us.	These are internal reference documents used to complete the datasheet and are for internal use only. All required information has already been included in the documents provided to you.
page 2	EXTERNAL DIMENSIONS (approximate)	W 2710 x H 2980 x D 1588	The dimensions of the equipment and its technical areas must be compatible with the available space in layout	The available space is indicated on DIN-01017-ANX-FD-0001_01 page 4, and the layout DWG file have already been shared with you. Please let us know if you need any further clarification.
page 2	MAX. HEAT DISSIPATED (kW)	4.2	We will state our Heat emission in the GA	Ok. The room HVAC calculation was based on this heat dissipation value. Higher values will require an evaluation by the HVAC team.

page 3	1	The furnace charge will consist of: -Glass beakers from 50 mL to 4 L; -125 mL to 3 L glass Erlenmeyer flasks; -100 mL to 2 L glass Shott bottle; -Aluminum seals; -Packages containing aluminum foil; -7.5 mL glass vials -Glass bottles from 53 mL to 45 L; -Packs of 12 mL glass vials -Glass beakers from 50 mL to 2 L; -Packs of 10 mL glass pipettes; -Packages of glass test tubes; -2 L glass volumetric flask	Without a clear definition of the load, we'll offer the biggest oven that fits the given space.	The required oven capacity is indicated on the datasheet (1.54 m³), compatible with the available layout. As a reference, we have the combination of the two loads shown in the adjacent image. The final load combination will be defined jointly between Butantan and the supplier during the detailed oven design phase.
page 3	2	It is essential that the supplier develops its own depyrogenation cycle for the materials presented in this document	The develope of the cycles is part of the PQ that usually is not in our scope. Anyway, we are offering support at a daily rate	See item 5.3.1
page 3	3	Access to the technical area will be through a technical door opening onto the circulation corridor (1017-3041). This door will have a 50 cm clearance. The applicant must indicate if there is another access to the equipment	Only 1 access from the side is ok. Be aware that the machine needs some space on top for the components	The clear height of the room is 3 meters. The equipment and its components must comply with this height limit.

page 3	Note 2	Considering the worst-case scenario.	Without a clear definition of the load, we cannot define a worst case scenario.	See line 7.
page 3	Note 3	Oven power: 57 kW. Control panel power: 1 kW.	Please clarify. Is this the available power in the room? What is this value? We'll state the amount of power neede for our equipment in the GA	Yes, this is the power capacity available in the room for this equipment. The building's electrical design was based on these values. Higher values will require an evaluation by the electrical team.

Documento Concluído - É obrigatória a utilização da folha de assinaturas anexa
ButanSign envelope ID: 734e155978f17caa6dd55e2f89de2a1f

FUNDAÇÃO BUTANTAN
Gestão é uma ciência

page 3	Note 7	Inlet temperature: 25°C. Outlet temperature: 35°C. (Return to the system not considered)	As requested, a sub loop will be in place	**Utility team:** O sistema de água abrandada não disponibiliza conexão para retorno do fluido, o equipamento deve prever o descarte ou loop de resfriamento. **Translation:** The softened water system does not provide a fluid return connection; the equipment must allow for drain discharge or an internal cooling loop.
page 3	Note 8	Supply temperature: 6°C. Return temperature: 12°C.	Please refer to the GA. With a Δ of only 6°C the flowrate is huge. Can you accept the return at 20°C ? In this case the flow rate will be 285 L/min with a pipe of 2", so about half the original requirement.	**Utility team:** Mesmo absorvendo a diferença de temperatura de retorno, não teríamos a vazão necessária para o equipamento (vazão disponível de 10 L/min, com conexão de 1/2") **Translation:** Even if the return temperature differential is absorbed, the available flow rate would not meet the equipment's requirements (available flow rate is 10 L/min, with a 1/2" connection size).
page 4		Room ceiling height 3.00m and access route height 2.90m. For equipment entry, 'turtles' or any other accessory for movement must be considered, without impacting the existing infrastructure/ceiling height. It is essential that during movement and installation in the area, the largest module of the equipment is 2.75 m high or less.	Please refer to GA. The height of the machine itself is lower than 3m and the dismounting il lower than 2,75m. But the total height of the equipment is higher than 3m because the inlet and the outlet are on top of the chamber.	The clear height of the room is 3 meters. The equipment and its components must comply with this height limit.

DESCRIÇÃO DA CARGA 1			
Quantidade	**Material**	**Quantidade**	**Material**
4	Béquer de 50 mL	6	Frasco Shott de 1000 mL
3	Béquer de 100 mL	2260	Selo de Alumínio
4	Béquer de 200 mL	2260	Frasco Ampola (vials) de 7,5 mL
4	Béquer de 250 mL	70	Frasco de 53 mL
2	Béquer de 500 Ml	40	Frasco de 200 mL
2	Béquer de 600 mL	40	Frasco de 250 mL
2	Béquer de 1000 mL	2	Proveta de 100 mL
2	Béquer de 2000 mL	2	Proveta de 500 mL
3	Béquer de 3000 mL	2	Proveta de 1000 mL
6	Béquer de 4000 mL	2	Proveta de 2000 mL
4	Erlenmeyer de 2000 mL	1	Pacote de pipeta de 10 mL
2	Erlenmeyer de 3000 mL		

Tabela 10: Descrição de carga 1

DESCRIÇÃO DA CARGA 2			
Quantidade	**Material**	**Quantidade**	**Material**
4	Erlenmeyer de 500mL	3	Proveta de 100mL
4	Pacotes de Frasco de 12mL c/ 10 unidades	3	Proveta de 500mL
2	Frasco de 9L	3	Proveta de 250mL
2	Frasco de 20L	3	Proveta de 50mL
2	Frasco de 45L	3	Frasco Shott de 2000mL
3	Frasco de 4L	3	Frasco de 5000mL
3	Pacotes de Tubo de Ensaio c/ 10 unidades	10	Pacote de Tubo de Ensaio p/ LF c/ 10 unidades
2	Balão de 2000mL	2	Erlenmeyer de 500mL c/ pérolas
4	Pacote de Erlenmeyer de 125mL	4	Pacote de alumínio c/ 7 fls
4	Erlenmeyer de 2000mL	10	Frasco Shott de 500mL
4	Proveta de 2000mL	20	Frasco Shott de 250mL
3	Proveta de 1000mL	10	Frasco Shott de 100mL

Tabela 15: Descrição de carga 2

		IB/ERU/CBI-0717-01 - Forno de despirogenização (ERU aprovada) (24-07-2025)		
3	References	ABNT ISO/TS17665-2 – Sterilization of medical devices – Steam. Part 2: Application guide from ABNT NBR ISO 17665- 1.	This normative refer to steam sterilization of medical devices and is not applicable to an oven	If is not applicable, ok.
3	References	ABNT NBR 16328:2024 Decree 8468/76 of September 8, 1976 State Decree No. 45,805/2001 DECREE No. 45,765, OF APRIL 20, 2001 Brazilian Pharmacopoeia IN No. 134/2022 IN No. 138/2022 IN No. 35/2019 DECREE No. 45,765, OF APRIL 20, 2001 State Decree No. 45,805/2001 Decree 8468/76 of September 8, 1976 RDC 658/2022	Local regulation will not considered for the design of the machine as we refer only to international one	As ANVISA is a participating authority in PIC/S, international standards (e.g., EU GMP / PIC/S GMP) are equivalent to Brazilian local regulations like RDC 658/2022,IN No. 138/2022 IN No. 35/2019. Please confirm that your standard design aligns with these international guidelines so we can validate compliance.

Fundação Butantan
Rua Alvarenga, 1396
Butantã, São Paulo/SP
CEP: 05509-002
www.fundacaobutantan.org.br

FUNDAÇÃO BUTANTAN
Gestão é uma ciência

5.1.2	GENERAL ITEMS	The company must be responsible for the following activities: • Pre-FAT • FAT; • Assembly • Commissioning; • Instrument calibration; • SAT; • Installation qualification; • Qualification of operation; • Thermal qualification; • Start up; • Performance qualification; • Training of maintenance team; • Operator training; • Development of cycles.	Actually those activities are in charge to the customer. Please refer to the quote for a dayly rate for the support of one technician or ours. • Thermal qualification; • Performance qualification; • Development of cycles.	See item 5.3.1
5.1.4	GENERAL ITEMS	All suppliers must request the layout file (dwg) of the equipment installation location, position their equipment, and send us the file, also in dwg format, for evaluation. The drawing must include the equipment, electrical panels, and any items occupying the space designated for the equipment. It is mandatory to respect the area reserved for the equipment	DWG required but not yet received. So the GA is done but the real connection to the walls and the overall W and D must be re-evaluated once the DWG will be supplied	The layout DWG file is available on Ariba.

5.1.6	GENERAL ITEMS	Along with the technical proposal, the supplier must submit a spreadsheet comparing the utilities required by the equipment for its full operation with the utilities we have available. If any of our utilities are insufficient, the supplier must indicate the impacts so that we can analyze them. If adjustments to the utilities are necessary, such as pressure or flow reduction, the supplier must also indicate this in the spreadsheet and include the necessary instruments and devices in the scope, as well as install these items near the equipment	Please refer to the GA. There are several utilities with missing info (for example instrument compressed air) and there are utilities completely insufficient to run the machine in a "normal" cycle time (for example the "ice water")	Instrument air is not available for this equipment, only process compressed air will be provided. The supplier must offer equipment compatible with the available utilities.
5.1.7	GENERAL ITEMS	The equipment must comply with the current RDC resolution (Good Manufacturing Practices for Medicines) and the current INs (Good Manufacturing Practices complementary to qualification and validation activities, Good Manufacturing Practices complementary to computerized systems used in the manufacture of medicines, and Good Manufacturing Practices complementary to sterile medicines).	Local regulation will not considered for the design of the machine as we refer only to international one	As ANVISA is a participating authority in PIC/S, international standards (e.g., EU GMP / PIC/S GMP) are equivalent to Brazilian local regulations like RDC 658/2022,IN No. 138/2022 IN No. 35/2019. Please confirm that your standard design aligns with these international guidelines so we can validate compliance.

5.1.14	GENERAL ITEMS	All surfaces in contact with clean processes and utilities must be passivated. Electropolished surfaces do not need to be passivated unless, after electropolishing, they have been altered (e.g., welded or mechanically polished) or exposed to external contamination	Please refer to 5.1.22 in this URS. Ra < 0,5 µm (SF1) is obtained mechanically with no need for electropolishing. So far, we are offering SF1.	See item 5.1.22.

5.1.20	GENERAL ITEMS	The following information must be indelibly affixed to the equipment using material appropriate to the room classification and resistant to the specified cleaning agents: - Company name, CNPJ (Brazilian tax ID), and address of the manufacturer or importer; - Information about type, model and capacity - Serial number or identification number, and year of manufacture - Registration number of the manufacturer/importer or of the legally qualified professional with the Regional Council of Engineering and Agronomy – CREA - Equipment weight - Operating and design temperature - Key electrical data	As per previous projects a standard nameplate will be installed to the machine. Those information will not be present on the nameplate: -CNPJ (Brazilian tax ID) -Registration number of the manufacturer/importer or of the legally qualified professional with the Regional Council of Engineering and Agronomy – CREA This info will be in the GA: -Equipment weight This info will be in the FS: -Operating and design temperature	To comply with mandatory Brazilian Regulatory Standard NR-12, equipment operational and safety data must be permanently visible on the machine itself. The following information must be indelibly affixed to the equipment: Manufacturer Name, Model, and Serial Number / Year Equipment Weight Operating and Design Temperatures Key Electrical Data
5.1.22	GENERAL ITEMS	The construction materials of surfaces that come into contact with the process or with clean utilities must meet the requirements of ASME BPE and the Brazilian Pharmacopoeia: Ra finish ÿ 0.5 µm with electropolishing. The supplier must issue a certificate proving the roughness required in this	Ra < 0,5 µm (SF1) is obtained mechanically with no need for electropolishing. So far, we are offering SF1. About the certificates: for the parts we polish in house we will provide a declaration, not a certificate	The construction materials of surfaces that come into contact with the process or with clean utilities must be electropolished with Ra < 0,5 µm. Documentation must include a traceable Roughness Inspection Certificate/Report.

5.1.28	GENERAL ITEMS	The supplier must perform a pre-FAT (Financial Transaction Authorization) check on the equipment and provide proof of its execution before the FAT check.	For FAT we mean Factory Acceptance Test	Yes, we confirm that FAT refers to the Factory Acceptance Test. It seems something was lost in translation from Portuguese to English, but we are referring to the same.
5.1.31	GENERAL ITEMS	The equipment's pre-FAT, FAT, and SAT protocols must include all static and/or dynamic tests necessary for the equipment to function correctly. If the supplier does not consider a particular test and the IB requests its inclusion during the protocol review, it should be included without any impact on the IB.	Our standard protocols are made to cover the majority of the market requests. If a custom test will be asked, a change order will be required at a defined daily rate	Regarding FAT/SAT testing, any tests required to verify compliance with our specification (URS), process parameters, and GMP/regulatory requirements must be included in the test protocols at no additional cost. If a requested test falls within the agreed technical scope and functionality of the equipment, it should not trigger a Change Order.

5.1.33	GENERAL ITEMS	The FAT (Field Technical Approval) may be rejected if it presents critical deviations related to performance, process, documentation, deviations/pending issues regarding routines and software, or if it does not fully meet the ERU (Environmental Regulation Unit). If the FAT is rejected, the equipment should not be shipped (sent to the client) until a new FAT is carried out and approved. In this case, the supplier will also be responsible for the accommodation, transportation, and food costs of the Butantan Institute technicians.	For FAT we mean Factory Acceptance Test For ERU we understood URS	Same as 5.1.28.

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

www.fundacaobutantan.org.br

FUNDAÇÃO BUTANTAN
Gestão é uma ciência

5.1.62	SPECIFIC CHARACTERISTICS	The equipment must have a network port, as well as a built-in printer, preferably in color (compatible with the cleanliness level of the room), for batch documentation/recording, such as: status, time, temperature, alarms, cycles, and programs	No local printer available	The equipment must have a built-in printer, preferably in color (compatible with the cleanliness level of the room).
5.1.72	SPECIFIC CHARACTERISTICS	The equipment must have a user-friendly interface on the front panel that displays information easily, as well as providing easy access to all required electrical components housed inside the cabinet.	Based on the room layout the cabinet can be in the front fascia panel (loading side) or in the tech area. Final position to be agreed.	It is preferable for it to be on the loading side.
5.1.74	SPECIFIC CHARACTERISTICS	The depyrogenation oven should have a technical area only on one side of the equipment; therefore, access for maintenance must be entirely from one side, and if it is necessary to access any inaccessible device, a removable technical panel must be provided on the equipment.	As per its construction, the machine should be accessible from both sides. Please refer to the General Arrangment	As indicated in DIN-01017-ANX-FD-0001_01_FornoDespirogenizacao_Assinada page 4 : Access to the technical area will be through a technical door opening onto the circulation corridor (1017-3041). This door will have a 50 cm clearance.

5.2.6	Quality Assurance – Equipment Qualification	Drawings of the equipment must be provided	Please confirm which drawing you are referring to. We will not share workshop drawings of the machine but only layouts as General Arrangement and Installation Plan	**Quality Assurance – Equipment Qualification:** Electrical drawings, P&ID and related drawings that can be used in order to confirm the correct installation of the equipment, as specified.
5.2.7	Quality Assurance – Equipment Qualification	The supplier must provide a Data Book for the equipment	Please clarify what do you mean with "data book"	**Quality Assurance – Equipment Qualification:** Spare parts list, I/O lists and every technical document that may help us understand and verify whether the equipment and its system is correctly installed and configured
5.2.11	Quality Assurance – Equipment Qualification	The system must have a technical specification.	As technical specification we supply the "Funcional Specification"	**Quality Assurance – Equipment Qualification:** OK
5.2.15	Quality Assurance – Equipment Qualification	Electronic record in a secure format that does not allow editing or deletion	Raw data are stored in a SQL database accessible only by the higher rights user	**Quality Assurance – Equipment Qualification:** OK
5.2.22	Quality Assurance – Equipment Qualification	The system must have architectural documentation	For "architectural documentation" we mean GA and IP	**Quality Assurance – Equipment Qualification:** OK
5.2.24	Quality Assurance – Equipment Qualification	A service contract should exist if development and maintenance services for the system are contracted	To be discussed / agreed. We have a rapresentative in Brazil that is Soleri. They are ablo also to perform maintenance.	**Quality Assurance – Equipment Qualification:** OK

5.2.25	Quality Assurance – Equipment Qualification	If critical data is entered manually into the system, the system must allow the data to be verified by another designated person or by some validated electronic means.	Any change of the registers, parameters, recipe, etc are password protected and are possible only to a user with high level of rights like supervisor or admin. There is not the possibility to have another person to approve the change.	**Quality Assurance – Equipment Qualification:** by this requirement, I mean double conference, with an electronic signature both from the executer and another from a supervisor
5.2.26	Quality Assurance – Equipment Qualification	The system must use the date and time from a reliable source to record events in the audit trail and/or in the electronic records themselves	As the machine is connected to your network and to your domain, the time syncronization will follow the policies in place	**Quality Assurance – Equipment Qualification:** OK
5.3.1	Quality Assurance – Thermal Qualification, Compressed Air and Special Gases	The work of developing cycles must be provided, where all loads determined by the user must be previously tested (at least 3 valid runs). This work is extremely important to adapt the equipment to the user's load types, ensuring that no program/recipe adjustments will occur during thermal qualification. This work is also a preparation for Thermal Qualification, therefore it should take place after Installation and Operation Qualification and before Thermal Qualification. The user must first define how many loads they intend to qualify on this equipment	This is a PQ (performance qualification) that usually is not in our scope. We will offer support from our technicians at a daily rate	**Quality Assurance - QTG:** The supplier must provide support for cycle development across all loads specified by the USER, testing these cycles with at least 3 valid runs. I believe one day of technical support will not be sufficient to assist in creating and executing these cycles/recipes. The USER is responsible for creating these cycles together with the equipment vendor, while the QTG department will only provide support for cycle creation.
5.3.2	Quality Assurance – Thermal Qualification, Compressed Air and Special Gases	For qualification purposes, the equipment must have side and/or top tri-clamp access for the passage of sensors (e.g., thermocouples, particle sensor). This access should not impact the temperature distribution and homogeneity within the equipment chamber	As standard the access is in the loading fascia panel	**Quality Assurance - QTG:** The supplier indicates that it is positioned on the panel face. The exact location for the thermocouple and endotoxin entry remains unclear. Kindly verify if a technical drawing can be provided specifying the location of this entry/pass-through for thermocouples and endotoxins.

5.3.3	Quality Assurance – Thermal Qualification, Compressed Air and Special Gases	The equipment must provide data externally (digitally and/or physically) for all installed recipes.	Please clarify. Do you mean a backup of the recipes?	**Quality Assurance - QTG:** Recipes shall be stored, and the equipment shall enable the extraction and printing of these recipes, along with the data from the studies conducted during the oven cycles.
5.3.4	Quality Assurance – Thermal Qualification, Compressed Air and Special Gases	The equipment must externally provide (digitally and/or physically) the data generated from the cycle at the end of each executed cycle.	Batch report in PDF stored in a folder in your server or printed over the network	**Quality Assurance - QTG:** The supplier meets this requirement. The equipment generates the batch report as a PDF, which can either be saved to a server folder or sent to a network printer.
5.3.5	Quality Assurance – Thermal Qualification, Compressed Air and Special Gases	Validator used in the execution of the Thermal Qualification protocol. Documentary proof must be provided for the intended use; the use of multimeters is prohibited. The maximum error should be specified in the technical specifications	This is a PQ (performance qualification) that usually is not in our scope. We will offer support from our technicians at a daily rate. It is supposed that the instruments for calibration will be provided by IB	**Quality Assurance - QTG:** The responsibility for thermal qualification rests with the equipment vendor. If the vendor does not perform the process, they must hire a Brazil-based company to execute the qualification. Furthermore, the equipment used in this procedure must comply with the established technical requirements, including the use of thermocouples that meet the previously mentioned error specifications.
5.3.6	Quality Assurance – Thermal Qualification, Compressed Air and Special Gases	Validator used in the execution of the Thermal Qualification protocol. For measurements performed with thermocouples, the maximum cold junction compensation error of the equipment should be 0.1°C.	This is a PQ (performance qualification) that usually is not in our scope. We will offer support from our technicians at a daily rate. It is supposed that the instruments for calibration will be provided by IB	**Quality Assurance - QTG:** The responsibility for thermal qualification rests with the equipment vendor. If the vendor does not perform the process, they must hire a Brazil-based company to execute the qualification. Furthermore, the equipment used in this procedure must comply with the established technical requirements, including the use of thermocouples that meet the previously mentioned error specifications.

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

www.fundacaobutantan.org.br

Documento Concluído - É obrigatória a utilização da folha de assinaturas anexa ButanSign envelope ID: 734e155978f17caa6dd55e2f89de2a1f

FUNDAÇÃO BUTANTAN
Gestão é uma ciência

5.3.7	Quality Assurance – Thermal Qualification, Compressed Air and Special Gases	Validator used in the execution of the Thermal Qualification protocol. The equipment must allow measurements using thermocouples and transmitters with inputs of 4 mA to 20 mA or 0 to 10 V simultaneously.	This is a PQ (performance qualification) that usually is not in our scope. We will offer support from our technicians at a daily rate. It is supposed that the instruments for calibration will be provided by IB	**Quality Assurance - QTG:** The responsibility for thermal qualification rests with the equipment vendor. If the vendor does not perform the process, they must hire a Brazil-based company to execute the qualification. Furthermore, the equipment used in this procedure must comply with the established technical requirements, including the use of thermocouples that meet the previously mentioned error specifications.
5.3.8	Quality Assurance – Thermal Qualification, Compressed Air and Special Gases	Validator used in the execution of the Thermal Qualification protocol. The computer and data protection equipment used for the acquisition, processing, reporting, storage, or retrieval of test data must meet the following requirements: The system software must be documented in sufficient detail and properly validated as suitable for use. Procedures for data protection must be established and implemented, which should include, but not be limited to, integrity and confidentiality of data entry or collection, storage, transmission and processing, access control and audit trail; The data acquisition equipment, including both hardware and software, must be protected against adjustments that would invalidate the test results	This is a PQ (performance qualification) that usually is not in our scope. We will offer support from our technicians at a daily rate. It is supposed that the instruments for calibration will be provided by IB	**Quality Assurance - QTG:** The responsibility for thermal qualification rests with the equipment vendor. If the vendor does not perform the process, they must hire a Brazil-based company to execute the qualification. Furthermore, the equipment used in this procedure must comply with the established technical requirements, including the data integrity requirement, in accordance with 21 CFR Part 11.

5.3.9	Quality Assurance – Thermal Qualification, Compressed Air and Special Gases	The applicant (supplier) must execute the Thermal Performance Qualification Protocol in Portuguese, which will be provided by the Qualification team of the Butantan Institute. The protocols will include the following tests	This is a PQ (performance qualification) that usually is not in our scope, neither the protocol writing because is strictly depends by the load definition and pattern. We will offer support from our technicians at a daily rate.	**Quality Assurance - QTG:** The thermal qualification protocol and its attachments, including the respective tests, are provided by IB, but executed by the equipment vendor using their own validator.
5.3.10	Quality Assurance – Thermal Qualification, Compressed Air and Special Gases	Signature Sheet A record of the collaborators who participated in the execution of the protocol.	This is a PQ (performance qualification) that usually is not in our scope. We will offer support from our technicians at a daily rate	**Quality Assurance - QTG:** The thermal qualification protocol and its attachments, including the respective tests, are provided by IB, but executed by the equipment vendor using their own validator.
5.3.11	Quality Assurance – Thermal Qualification, Compressed Air and Special Gases	Verification of Measuring Equipment Verify that the equipment and instruments used in performing the Thermal Qualification tests are calibrated and have calibration certificates available.	This is a PQ (performance qualification) that usually is not in our scope. We will offer support from our technicians at a daily rate	**Quality Assurance - QTG:** The thermal qualification protocol and its attachments, including the respective tests, are provided by IB, but executed by the equipment vendor using their own validator.
5.3.12	Quality Assurance – Thermal Qualification, Compressed Air and Special Gases	Qualification results Summary of the results of the activities performed during the Thermal Qualification.	This is a PQ (performance qualification) that usually is not in our scope. We will offer support from our technicians at a daily rate	**Quality Assurance - QTG:** The thermal qualification protocol and its attachments, including the respective tests, are provided by IB, but executed by the equipment vendor using their own validator.
5.3.13	Quality Assurance – Thermal Qualification, Compressed Air and Special Gases	Record of Evidence Record all evidence generated during Thermal Qualification (e.g., data and graphs from the validator system, furnace data, calibration certificates).	This is a PQ (performance qualification) that usually is not in our scope. We will offer support from our technicians at a daily rate	**Quality Assurance - QTG:** The thermal qualification protocol and its attachments, including the respective tests, are provided by IB, but executed by the equipment vendor using their own validator.

5.3.14	Quality Assurance – Thermal Qualification, Compressed Air and Special Gases	Incident Registration Record all events generated during Thermal Qualification	This is a PQ (performance qualification) that usually is not in our scope. We will offer support from our technicians at a daily rate	**Quality Assurance - QTG:** The thermal qualification protocol and its attachments, including the respective tests, are provided by IB, but executed by the equipment vendor using their own validator.
5.3.15	Quality Assurance – Thermal Qualification, Compressed Air and Special Gases	Verification of Equipment Instrument Calibration Verify that the equipment to be qualified and its measuring instruments are calibrated across the process range and have available calibration certificates.	This is a PQ (performance qualification) that usually is not in our scope. We will offer support from our technicians at a daily rate	**Quality Assurance - QTG:** The thermal qualification protocol and its attachments, including the respective tests, are provided by IB, but executed by the equipment vendor using their own validator.
5.3.16	Quality Assurance – Thermal Qualification, Compressed Air and Special Gases	Calibration of the temperature sensors used in the execution of the Thermal Qualification protocol. Temperature sensors (thermocouples) must be calibrated across the equipment's process range before the thermal qualification protocol can begin The calibration should have an error of ÿ0.5°C.	This is a PQ (performance qualification) that usually is not in our scope. We will offer support from our technicians at a daily rate	**Quality Assurance - QTG:** The thermal qualification protocol and its attachments, including the respective tests, are provided by IB, but executed by the equipment vendor using their own validator.
5.3.17	Quality Assurance – Thermal Qualification, Compressed Air and Special Gases	Verification of the temperature sensors used in the execution of the Thermal Qualification protocol After all thermometric measurements have been taken, the thermocouples must have their calibration verified. The calibration verification must show an error ÿ0.5°C.	This is a PQ (performance qualification) that usually is not in our scope. We will offer support from our technicians at a daily rate	**Quality Assurance - QTG:** The thermal qualification protocol and its attachments, including the respective tests, are provided by IB, but executed by the equipment vendor using their own validator.
5.3.18	Quality Assurance – Thermal Qualification, Compressed Air and Special Gases	Equipment Parameter Log Register the parameters of all qualified programs	This is a PQ (performance qualification) that usually is not in our scope. We will offer support from our technicians at a daily rate	**Quality Assurance - QTG:** The thermal qualification protocol and its attachments, including the respective tests, are provided by IB, but executed by the equipment vendor using their own validator.

5.3.19	Quality Assurance – Thermal Qualification, Compressed Air and Special Gases	Temperature Distribution Study – Empty Chamber Ensure that the equipment exhibits a homogeneous temperature distribution and this should be performed in triplicate for each type of recipe developed. A geometric distribution of 11 sensors within the equipment chamber should be considered, and 1 sensor should be positioned close to the equipment's temperature control sensor This test must meet the following acceptance criteria: The temperature variation between the sensors during the exposure phase should not exceed ±15°C from the setpoint.	This is a PQ (performance qualification) that usually is not in our scope. We will offer support from our technicians at a daily rate	**Quality Assurance - QTG:** The thermal qualification protocol and its attachments, including the respective tests, are provided by IB, but executed by the equipment vendor using their own validator.
5.3.20	Quality Assurance – Thermal Qualification, Compressed Air and Special Gases	Temperature Penetration Study – Load Chamber To ensure the effectiveness of the sterilization/depyrogenation process through temperature penetration into the load. This test should consider the distribution of 11 sensors positioned within the load, with 1 sensor positioned near the equipment's control sensor. In order to evaluate the efficiency of the cycle, bioindicators/endotoxins should be distributed along with the sensors inserted into the cargo. This test must be performed in triplicate for each load developed and must meet the following acceptance criteria: - All bioindicators/endotoxins must be inactivated - The minimum cumulative lethality must be ÿ 30 equivalent minutes (The reference temperature for calculating the equivalent time is 170°C for Dry Heat Sterilization and 250°C for Depyrogenation).	This is a PQ (performance qualification) that usually is not in our scope. We will offer support from our technicians at a daily rate	**Quality Assurance - QTG:** The thermal qualification protocol and its attachments, including the respective tests, are provided by IB, but executed by the equipment vendor using their own validator.

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

www.fundacaobutantan.org.br

FUNDAÇÃO BUTANTAN
Gestão é uma ciência

5.3.21	Quality Assurance – Thermal Qualification, Compressed Air and Special Gases	Data Integrity Verification Check if: - All employees who performed activities within the qualification protocol were registered. - All fields in the protocol, including those for signature, have been properly completed or cancelled (where applicable). - All blank fields in the protocol have been invalidated/cancelled - All tests were completed at the time of test execution to ensure that the TRUSTED data is ORIGINAL, CONTEMPORARY, and correctly the test executor. ATTRIBUTED to - All data entered into the protocol must be legible. - All erasures and corrections must be legible and corrected, respectively. - All tests were duly verified by a qualified and trained employee.	This is a PQ (performance qualification) that usually is not in our scope. We will offer support from our technicians at a daily rate	**Quality Assurance - QTG:** The thermal qualification protocol and its attachments, including the respective tests, are provided by IB, but executed by the equipment vendor using their own validator.
5.3.22	Quality Assurance – Thermal Qualification, Compressed Air and Special Gases	After the Thermal Qualification tests are carried out, a report must be issued containing a summary of the study results and the instruments used, and this report must be approved by the Qualification team of the Butantan Institute.	This is a PQ (performance qualification) that usually is not in our scope. We will offer support from our technicians at a daily rate	**Quality Assurance - QTG:** The thermal qualification report must be prepared by the equipment vendor, including a summary of the study results and the instruments used, and this report must be approved by the Qualification team of the Butantan Institute.

5.6.2.	Metrology	Calibrations must be accredited by Inmetro/RBC	RBC Inmetro (Brazil) and Accredia (Italy) are part of the International Laboratory Accreditation Cooperation (ILAC- MRA), so there is a mutual recognition of the certificates issued by them. This means that a certificate issued by Accredia is recognized by RBC Inmetro and vice versa.	**Metrology team:** Conforme especificado no item 5.6.1 a calibração dos instrumentos críticos devem ser realizadas após a instalação do equipamento na fábrica. **Translation:** As specified in item 5.6.1, the calibration of critical instruments must be performed after the installation of the equipment at the plant.
5.6.3	Metrology	Calibrations must be performed within the process range with the minimum number of points below: -Pressure on an analog instrument: 10 points, rise and fall. -Pressure on digital instrument: 5 points -Temperature: 03 points	As standard is offered a calibration prior the SAT the includes: - 3 points for the analogic instrument (rise and fall are N/A for this instrument) - set and reset point, rise and fall for the digital instrument - 3 points for the temperature probe	**Metrology team:** A calibração deve seguir as especificações do item 5.6.3. **Translation:** The calibration must follow the specifications in item 5.6.3.

5.8.2	Information Technology – IT Infrastructure	Software should preferably be provided in web format; if this is not possible, it should be in a client/server model.	The WEB format is not available. As per the other IT requirement we think the most appropiate level of automation is 2.	Since a WEB-based platform is not available, the architecture can be presented in a virtualized client/server model.
5.8.4	Information Technology – IT Infrastructure	Creation of an Application and Database Development/Staging Environment for validation and necessary changes to ensure the applications function correctly in production.	Please clarify. There is not a developement ambient. The developed recipes are released for production by an user that has the rights to do it. The operator can only run what the other user released.	If the configurations/tasks are not executed on the server, but directly on the equipment, and there is no possibility of using a staging environment, this item may be disregarded.
5.8.7	Information Technology – IT Infrastructure	If a computer is required to operate the software, it must have a Core i7 processor or higher, 8GB of RAM, at least 500GB of SSD storage, be compatible with Microsoft Windows 10 Pro or higher on a 64-bit platform, and be ready for use, including all necessary licenses and accessories for proper functioning.	The standard HMI is an IPC PX-39A - Intel Xeon W-11155MLE - Ram 32 GB - SSD 256 GB - Windows 11 Please clarify if the amount of storage is OK	If the specified OS is for the client machine, Win11 Pro is acceptable. However, if it is for the server in the client/server architecture, it must be Windows Server 2022 or higher. The 256GB drive may be retained if, upon completion of the OS and application installation, storage usage remains below 50%. If usage exceeds 50%, an upgrade to 500GB will be required.

5.8.12	Information Technology – IT Infrastructure	In case of any impediment to installing security tools such as antivirus software, provide documentation for the secure connection of the equipment to the industrial or corporate network Provide warranty coverage for repair and recovery in case of any incident due to lack of antivirus software or inability to update the Operating System	We will be happy to support you for the installation of your antivirus. Anyway, we are using standard Siemens HW and SW. The compatibility with a specific antivirus should be evaluated with Siemens	The supplier should support the antivirus installation process and, if any problems arise, revert the installation to its original state and then help contact Siemens to resolve the issue.

5.8.15	Information Technology – IT Infrastructure	If a switch is required, especially an industrial one that will be connected to PLCs, it must meet, according to the switch manufacturer, in addition to the requirements of the Automation Engineering discipline, at least the following requirements and equivalent protocols: Supports management via web, console, telnet and/or ssh, supports 4096 VLANs, access, trunk and hybrid port modes, supports 1G single-mode fiber, supports EtherChannel, static and interVLAN routing, DLR, MRP, REP (Static Ethernet Protocol), STP/RSTP	The standard switch is unmanaged, 10/100 Mbit/s. Please clarify is a managed one is mandatory.	If the switch is for communication with the Butantan network infrastructure, it must follow the provided standard. However, if it is for communication between the furnace and an HMI or computer controlling it, it can remain as offered.

5.9.2	Process Automation	The PLC software should be fully commented, preferably in Portuguese	The SW is commented in English only	**Process Automation:** Ok
5.9.5	Process Automation	The PLC should provide the F0 calculation	Actually for the dry heat sterilization the parameter is called Fh	**Process Automation:** Ok

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

www.fundacaobutantan.org.br

FUNDAÇÃO BUTANTAN
Gestão é uma ciência

5.9.7	Process Automation	The HMI scripts should be fully commented, preferably in Portuguese	The SW is commented in English only	**Process Automation:** Ok
5.9.9	Process Automation	The system provided must meet the requirements of the ANVISA Software Validation Guide, the GAMP 5 standard, and CFR 21 part 11, which guarantee the traceability and security of the information (records) existing in the computerized system.	The local regulation are not considered on the developing of our SW. So we will follow the GAMP5 and CFR 21 part 11	**Process Automation:** It is necessary to comply with all requirements of the cited standards.
5.9.10	Process Automation	The system must be able to work simultaneously with other equipment (receiving and sending data) installed in the factory that requires integration with the system to be provided	Please define which other system should commuicate with our equipment and in which way. So far, without details, nothing is foreseen in the offer	**Process Automation:** It can operate simultaneously with the other automation systems, mainly the Process and Utilities systems, via the Ethernet communication protocol. This will be addressed later as per item 5.9.13.
5.9.12	Process Automation	The equipment must have Layer 2 managed connection switch(es), with at least 2 GB ports and comply with the industrial protocols CIP, Ethernet/IP, Profinet and/or Modbus/TCP with NAT support.	Please refer to 5.8.15 The standard switch is unmanaged, 10/100 Mbit/s.	**Process Automation:** It is necessary to replace the switch with a Layer 2 managed model that supports the mentioned network protocols.
5.9.13	Process Automation	A list (Communication Table) must be provided with data and parameters that can be exported (sent/requested) for communication with other systems on the Butantan site, as well as network information, protocol, electrical standard, physical medium, etc., necessary for communication	The exchange table will be agreed during the design phase	**Process Automation:** Ok
5.9.14	Process Automation	The system should generate and share charts and reports with information necessary for the user, such as: production data for a given period, trend charts, system performance reports, configurations, audit trail, alarm and fault reports, among others.	Charts and reports are in the batch report in PDF.	**Process Automation:** Ok

5.9.16	Process Automation	The supplier shall provide all signal, power, and network cables, as well as all pneumatic hoses, if necessary, and other materials used in the automation system for interconnecting devices, instruments, sensors, and equipment with the automation panels	The machine will be fully assembled and cabled for its functioning. No other cables or hoses will be provided	**Process Automation:** Ok
5.10.6	Utilities (Projects & Works)	The supplier is responsible for providing the necessary adapters and flexible fittings for installation and connection to the available utility point	Please clarify. Usually the connection to the utilites is not in our scope	The connection of the equipment to the utility points will be performed by the site installation contractor.

5.16.7.	Information Technology – Information Security	Remote access to the equipment or solution must be performed using the Secure Password tool, considering supervised access, proper traceability, as well as temporary access for the time necessary to perform the activity. Access must be granted and revoked after it has been activated.	We will be happy to support you for the installation of your super Password tool. Anyway, we are using standard Siemens HW and SW. The compatibility with a specific software should be evaluated with Siemens	Remote access to any equipment must be approved by Information Security. The Information Security team may deny any access model that is not approved or authorized at Butantan. Authorized access is granted through Segura PAM.

5.17.1	Information Technology – IT Support	If the proposed platform requires a computer to operate the software, it must have a Core i7 processor (or superior processor), 8GB of RAM, a 500GB SSD, be compatible with the Microsoft Windows 10 Pro operating system or, preferably, Windows 11 Pro on a 64-bit platform, and be ready for use, including the necessary licenses and accessories for proper functioning.	Please refer to 5.8.7 The standard HMI is an IPC PX-39A - Intel Xeon W-11155MLE - Ram 32 GB - SSD 256 GB - Windows 11 Please clarify if the amount of storage is OK	See item 5.8.7
5.17.2	Information Technology – IT Support	If there are peripherals such as printers, readers, and others, their installation and configuration must be carried out by the contracted company	No phariphals connected to the machine	**Information Technology – IT Support:** Ok.
5.17.3	Information Technology – IT Support	If computer use is required, the minimum and desired requirements must be provided by the supplier so that, for standardization purposes, the feasibility of [providing computer services] can be assessed Use of a standard computer provided by IT. Only in cases where the computer configuration is very specific and cannot be provided by IT, may it be added to the project to be delivered by the supplier, and even then subject to evaluation by IT.	External computer is not required	**Information Technology – IT Support:** Ok.

São Paulo, 13 de agosto de 2026.

COMISSÃO DE LICITAÇÃO

Documento Concluído - É obrigatória a utilização da folha de assinaturas anexa ButanSign envelope ID: 734e155978f17caa6dd55e2f89de2a1f

BUTANSIGN

FUNDAÇÃO BUTANTAN
Gestão é uma ciência

Resposta de esclarecimento - Rodada 02_13082026_123710

Denise de Abreu Carpinteiro
368.566.768-83

Código do documento
734e155978f17caa6dd55e2f89de2a1f

Assinaturas

Denise de Abreu Carpinteiro
denise.carpinteiro@fundacaobutantan.org.br

Eventos do documento

13 Aug 2026, 12:37:13
Documento **criado** por: Denise de Abreu Carpinteiro. Email: denise.carpinteiro@fundacaobutantan.org.br. DATE_ATOM: 2026-08-13T12:37:13-03:00

13 Aug 2026, 12:37:45
Documento **assinado** por: Denise de Abreu Carpinteiro (Fundação Butantan) . Email: denise.carpinteiro@fundacaobutantan.org.br - IP: 2.16.108.56. DATE_ATOM: 2026-08-13T12:37:45-03:00

Hash do documento original

(md5) e782696f35e40c9d63c25b35156eed2c
(sha256) bbbb00bf75ebb773b4a2af30d3c0f8225bc06b3ec8251dc518ecf009648b1f51

Este log pertence **única** e **exclusivamente** aos documentos de HASH acima.
Este documento está assinado e certificado por Butansign
Validar documento em: https://fundacaobutantan.org.br/assinaturas/confirmacao