

Temos International Healthcare Accreditation (TIHA)

Final Report Temos Assessment

Certificate of Compliance: COVID-19 Safe Minimizing the risk of COVID-19 transmission in healthcare organizations

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Executive Summary

Assessment methodology

The assessment is based on:

- Temos International Healthcare Accreditation Standards for Certificate of Compliance: COVID-19 Safe, version 2.0
- Temos Certification Chart (TCC), dated 23 November 2020
- Reference documents and evidence provided
- Assessment by the Temos assessors' team from 23 November 2020 to 30 January 2021
- Program's Self Evaluation Tool (SET), dated 22 January 2021 (2nd version)

Assessors' team

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Summary

Asklipios SA Psychiatric Clinic meets the Temos requirements of the TIHA Standards for Certificate of Compliance: COVID-19 Safe, version 2.0 with good grading (Classification B).

Asklipios SA Psychiatric Clinic in Veroia, Greece, applied for Temos certification against the standards of the "Certificate of Compliance: COVID-19 Safe - Minimizing the Risk of Transmission".

The organization was classified as secondary care facility offering mental healthcare and respective services for patients. From 23th November 2020 to 30th of January 2021, a desktop assessment was conducted by two assessors from Germany and Greece to determine the category of grading.

Asklipios SA Psychiatric Clinic adequately complies with the Temos standards under the program "Certificate of Compliance: COVID-19 Safe - Minimizing the Risk of Transmission" with minor deviations which should be appropriately treated as indicated in the different chapters of this report.

Congratulations to the entire team on this achievement!



Results and findings

The appraisement of the various areas - differentiated by the chapters as given in the Temos International Healthcare Accreditation (TIHA) Standards - is as follows:

- Standards that were rated as "fully met" or "met" are only listed if there is a recommendation or comment assigned to it from assessors' side.
- Standards that were either "partially met" or "not met" are listed and the respective assessors' demands, recommendations and comments are summarized.
- Standards that were assessed as not applicable are listed, too, with the respective notification "not applicable".

Where applicable and in addition, you find at the end of every chapter further recommendations and/or comments from the assessors that are not assigned to individual standards but which you may consider for implementation in order to further improve your services.



Final Result

Α	В	С	D	N/A	Valid Ra	atings	Final Re	esult			
0	5	0	0	1	6/6		B: Pass	ed "Good	" with mine	or non-confo	rmities
Chapter		Fully Met	Met	40 M - 11-14-0		Not Met	Not Applicable	Not Assessed	Valid Ratings	Percentage	Chapter Rating*
SIP		4	6	2	C)	6	0	18 / 18	75 %	В
HRSE		5	4	2	С)	1	0	12 / 12	77.27 %	В
PCC		4	4	2	C)	1	0	11 / 11	75 [%]	В
FET		3	3	1	C)	5	0	12 / 12	78.57 %	В
TTS		0	0	0	C)	9	0	9/9	0 %	N/A
CCO		0	2	0	С)	0	0	2 / 2	75 [%]	В

(*) Chapter Rating:

- A: Excellent achievement
- B: Good achievement
- C: Fair achievement
- N/A: Not applicable
- D: Poor achievement



Section 1 - Temos Certification Standards

Chapter 1 - Standard Infection Prevention Measures during COVID-19 Outbreak: Standard Precautions and Transmission-based Precautions (SIP)

Temos rating: B (good achievement)

SIP 1	Standard measures					
SIP 1.1	Policies and procedures for prompt identification and isolation of infected and/or sick people are in place to assure:					
	 Prompt identification and isolation of potentially infectious individuals. This process includes screening measures by especially trained staff at the entrance (s) of the facility for every visitor, patient or healthcare professional unless a special health certificate is available and has already been submitted to the hospital (clinic, medical center, and the like). See Chapter 3 for further details. Provision of PPE to limit spread of the respiratory secretions. Isolation of people suspected of having COVID-19 including restricted access of staff entering isolation areas. 					
	Temos rating: met					
	<u>Assessors' findings:</u> There is a general standardised document (SOP 5-2) where precautions and measures are explained for the screening and early identification of SARS-CoV-2 both for the patients and staff.					
	 <u>Assessors' demands:</u> 1. Provide a description of the standard screening process of the staff. It is mentioned that this takes place every 15 days but there is no additional information or evidence provided (e.g. sampling, collaborating laboratory for the tests, delivery of test results, etc.). 2. Define a healthcare professional responsible for the regular personnel screening. 3. Provide evidence for the submission and approval of the clinic's infection control and preventionwritten program. Please provide the section where the isolation measures are explicitly described. 					
SIP 1.4	Visual alerts such as signs and posters at entrance(s) and at strategic places provide instructions on hand hygiene, respiratory hygiene, and cough etiquette. Respiratory etiquette is also encouraged by information leaflets, charts, etc.					
	Temos rating: met					
	<u>Assessors' findings:</u> The provided material does not include references to the appropriate cough etiquette.					
	Assessors' demands: Males are that there are instructions down a structure data the staff and a stimute related					

Make sure that there are instructions demonstrated to the staff and patients related to cough etiquette.



SIP 1.6	Physical barriers, such as clear plastic sneeze guards are installed where possible and applicable.					
	Temos rating: met					
	<u>Assessors' remarks:</u> Evidence was provided for the installation of sneeze guards as part of evidence provided for standard HRSE 2.3.					
SIP 1.7	Frequently touched objects and surfaces such as workstations, keyboards, telephones, handrails, and doorknobs are regularly cleaned and disinfected. A respective hygiene plan is in place; cleaning and disinfection is documented and supervised. The organization applies cashless payment procedures where possible.					
	 Explanatory note: Dirty surfaces should be cleaned with soap and water prior to disinfection. When choosing cleaning chemicals, the hospital/clinic should consult information on Environmental Protection Agency (EPA)-approved disinfectant labels (or from similar renowned organizations) which are registered by the respective local agency for medical drugs and devices with claims against emerging viral pathogens. Products with EPA-approved emerging viral pathogens claims are expected to be effective against SARS-CoV-2 based on data for harder to kill viruses. Follow the manufacturer's instructions for use of all cleaning and disinfection products (e.g., concentration, application method and contact time, PPE). The European Center for Disease Prevention and Control (ECDC) published that in case of a shortage of hospital disinfectants, surfaces may be decontaminated with 0.05% sodium hypochlorite (dilution 1:100 if household bleach at an initial concentration of 5% is used) after cleaning with a neutral detergent. Surfaces that do not tolerate sodium hypochlorite should be cleaned with a neutral detergent, followed by 70% ethanol. 					
	Temos rating: partially met					
	<u>Assessors' findings:</u> It is mentioned that these objects are disinfected but there is no evidence that shared use is prevented. Office equipment is not explicitly mentioned on the cleaning checklists.					
	<u>Assessors' demands:</u> Office equipment disinfection shall be mentioned in detail on the cleaning checklists to prove compliance with the hygiene plan as well as with this standard.					
SIP 1.8	Magazines, reading materials, toys and other objects that may be touched by others and which are not easily disinfected are removed.					
	Temos rating: met					
	<u>Assessors' findings:</u> It is mentioned that these types of objects are disinfected on a daily basis but without clarifying the frequence of disinfection and cleaning in between after the use by different patients.					
	<u>Assessors' demands:</u> Establish specific intructions for the cleaning and disynfection of objects which may					



	be frequently used/ touched by the patients, referring to those which are used in the frame of their therapeutic sessions. Other unecessary objects should be removed.				
SIP 1.9	Ambulances and other vehicles used for patient transportation are equipped with hand hygiene and disinfection products, paper towels and waste bags.				
	Temos rating: not applicable				
SIP 1.10	The interiors of ambulances and other vehicles used for patient transportation are carefully cleaned and disinfected every time they have been used by a patient. Respective documentation is available.				
	Temos rating: not applicable				
SIP 1.11	Regular ventilation improves hygiene and air quality, as the number of pathogens in the air can increase in enclosed spaces. Ventilation reduces the number of very fine droplets containing pathogens that may be present in the air.				
	Remark on air conditioning: According to the current state of scientific knowledge, the risk of infection via air conditioning is considered low overall. Switching off air conditioning is not recommended, particularly in rooms where infected persons are treated or where infectious material is handled, as doing so can lead to an increased airborne aerosol concentration and thus greater risk of infection. Air flow patterns and air currents should be considered for the movement of any droplet transmission. Regular sanitation, disinfection, and maintenance of the air conditioning system(s) is mandatory to assure respective air quality.				
	Temos rating: partially met				
	<u>Assessors' findings:</u> Physical air flow is recommended as stated in the cleaning and hygiene plan of the clinic. Nevertheless, there is no sufficient information about the internal air cleanliness guidelines and the ventilation systems used, especially in winter time where heating systems are in use and windows cannot be kept open.				
	<u>Assessors' demands:</u> Provide a clear description about the internal air flow including how cleanliness is ensured. For example, if air conditioning units are used there must be documented information available about the planning and implementation of maintenance, filter replacement, disinfection, and the like.				
SIP 3	Respirators A respirator is a device designed to protect the wearer from inhaling hazardous atmosphere, including fumes, vapors, gases and particulate matter such as dusts and				

atmosphere, including fumes, vapors, gases and particulate matter such as dusts and airborne microorganisms. There are two main categories: the air-purifying respirator, in which respirable air is obtained by filtering a contaminated atmosphere, and the airsupplied respirator, in which an alternate supply of breathable air is delivered. Within each category, different techniques are employed to reduce or eliminate noxious airborne contaminants.

SIP 3.1 Staff members, including those who work within 1.5 m (6 feet) of patients known to be,



or suspected of being, infected with SARS-CoV-2 and those performing aerosol-generating procedures, use respirators.

Temos rating: not applicable

Assessors' findings:

Asklipios is a mental health inpatients' facility where patients with COVID-19 are not admitted and where aerosol-generating interventions are not taking place. Respirators are not used in the clinic. Therefore, the assessors consider this standard as not apliccable.

SIP 3.2

Nationally or internationally (e.g. by the National Institute for Occupational Safety and Health (NIOSH) or by the European Union) approved, N95 filtering facepiece respirators, FFP2-standard masks set, or better must be used in the context of a comprehensive, written respiratory protection program that includes fit-testing, training, and medical diagnostic tests.

Remark - respirators:

When disposable N95 filtering facepiece respirators are not available, consider other respirators that provide greater protection and improve the user's comfort. OHSA; NIOSH, and CDC recommend as acceptable: R/P95, N/R/P99, or N/R/P100 filtering facepiece respirator; an air-purifying elastomeric (e.g. half-face or full-face) respirator with appropriate filters or cartridges; powered air purifying respirator (PAPR) with high-efficiency particulate arrestance (HEPA) filter; or supplied air respirator (SAR). Consider using PAPRs or SARs for any work operations or procedures likely to generate aerosols (e.g. cough, induction procedures, some dental procedures, invasive specimen collection, blowing out pipettes, shaking or vortexing tubes, filling a syringe, centrifugation).Face shields may also be worn on top of a respirator to prevent bulk contamination of the respirator.

Type of air-purifying respirators that protect by filtering particles out of the air the user is breathing according to NIOSH:

- 1. N95 Filters at least 95% of airborne particles. Not resistant to oil.
- 2. Surgical N95 A NIOSH-approved N95 respirator that has also been cleared by FDA as a surgical mask.
- 3. N99 Filters at least 99.97% of airborne particles. Not resistant to oil.
- 4. N100 Filters at least 95% of airborne particles. Not resistant to oil.
- 5. R95 Filters at least 95% of airborne particles. Somewhat resistant to oil.
- 6. P95 Filters at least 95% of airborne particles. Strongly resistant to oil.
- 7. P99 Filters at least 99% of airborne particles. Strongly resistant to oil.
- 8. P100 Filters at least 99.97% of airborne particles. Strongly resistant to oil.

Remark - 3D-printing:

According to FDA it is possible to use 3D-printing to make certain PPE. However, there are technical challenges that have to be overcome to be effective enough. For example, 3D-printed PPE may provide a physical barrier, but 3D-printed PPE are unlikely to provide the same fluid barrier and air filtration protection as FDA-cleared surgical masks and N95 respirators.

Temos rating: not applicable

Assessors' findings:

COVID-19 patients are not admitted to the clinic and those with suspicious symptoms



are isolated and transferred to the public hospital. The assessors consider this standards as not applicable.

SIP 3.3 In case both respiratory protection and resistance to blood and body fluids is needed a surgical N95 respirator or similar is used.

Temos rating: not applicable

Assessors' findings:

COVID-19 patients are not admitted in the clinic and those with suspicious symptoms are isolated and transferred to the public hospital. No surgical or other interventions take place in the clinic. The assessors consider this standards as not applicable.

SIP 3.4 Healthcare staff receive training on and demonstrates an understanding of:

- 1. Selection of respirators.
- 2. Use (including donning and doffing) of respirators.
- 3. How to do a user seal check (fit check).
- 4. Proper disposal or disinfection of respirators.
- 5. Inspection for damage.
- 6. Maintenance of respirators.
- 7. The limitations of respiratory protection equipment.

Temos rating: not applicable

<u>Assessors' findings:</u> Respirators are not used in the clinic.

Chapter 2 - Management of Human Resource and Provision of a Safe Workplace Environment (HRSE)

Temos rating: B (good achievement)

HRSE 1	Human Resources Management			
HRSE 1.3	When creating shift schedules, the same employees are assigned to shared shifts (where possible). In case contact is unavoidable, this happens between the same individuals and allows tracking within a defined group in case of need.			
	Temos rating: partially met			
	<u>Assessors' findings:</u> There was no evidence submitted about how the clinic covers this standard.			
	<u>Assessors' demands:</u> Develop a policy or similar standard document for the shift planning in compliance with this standard.			
HRSE 1.5	Nurses and doctors who have recently recovered from a COVID-19 infection should be the preferred personnel providing care since they may have some protective immunity.			
	Temos rating: not applicable			



Assessors' findings:

There has been no case of COVID-19 infected healthcare professionals in the clinic. The standard is considered as not applicable.

HRSE 2 Safety Measures for Workplaces

HRSE 2.4 The organization discourages staff from using other colleagues' phones, desks, offices, or other work tools and equipment, when possible.

Temos rating: partially met

Assessors' findings:

As part of the clinic's hygiene and cleaning policy it is mentioned that these objects are disinfected but there is no evidence that shared use is prevented.

Assessors' demands:

Actively promote the hygiene measures for the staff working in office positions. Make clear that office objects should not be shared among the colleagues.

Chapter 3 - Patient-centered Care during COVID-19 Outbreak – Screening and Clinical Management (PCC)

Temos rating: B (good achievement)

PCC 1 Before care and treatment starts: Screening for COVID-19 status and triaging

PCC 1.5 If a patient is arriving via transport by emergency medical services (EMS), EMS personnel contacts the receiving emergency department (ED) or healthcare facility and follows previously agreed upon local or regional transport protocols. This will allow the healthcare facility to prepare for receipt of the patient.

Temos rating: not applicable

<u>Assessors' findings:</u> Asklipios is a mental health inpatients clinic. There is no emergency service provided to patients. Inpatients are admitted based on a prescheduled appointment. The assessors rated this standard as not applicable.

PCC 2 Upon arrival and during the visit: Screening for COVID-19 status and patientcentered care

PCC 2.1 Patients are systematically assessed at the time of check-in/entering the facilities. The patient is asked about the presence of symptoms of a respiratory infection and history of travel to areas experiencing transmission of COVID-19 or contact with possible patients with COVID-19. If the patient is afebrile (temperature < 38° C, < 100.4° F, alertness temperature > 37° C, > 98.6° F for adults) and otherwise without symptoms consistent with viral infection, e.g. COVID-19, care is provided using appropriate engineering controls, work practices, and infection control practices as described above and defined in the organization's infection prevention policy. Sick patients are placed in a private room (isolation) as quickly as possible.



Remark:

First meta-analysis data found that the main clinical symptoms of COVID-19 patients were fever (88.5%), cough (68.6%), myalgia or fatigue (35.8%), expectoration (28.2%), and dyspnea (21.9%). Minor symptoms include headache or dizziness (12.1%), diarrhea (4.8%), nausea and vomiting (3.9%). The results of the laboratory showed that the lymphocytopenia (64.5%), increase of C-reactive protein (44.3%), increase of lactic dehydrogenase (28.3%), and leukocytopenia (29.4%) were more common. There are also patients with no or no specific symptoms.

Temos rating: met

Assessors' findings:

According to the provided documentation the reception staff is responsible for the screening of the patients upon their entrance to the clinic. Although the followed procedure is based on the appropriate steps and the questionnaire that is used is in accordance with the international standards and protocols, there is no healthcare professional involved in the screening process before the initial clinical assessment of the patient. Especially, in the case of psychiatric patients, communication may be compromized due to the psychological condition of the patient. In this case, a healthcare professional should be asked to control the patient and ensure an accurate screening process.

Assessors' demands:

A healthcare professional should be responsible for the screening procedure of the patients admitted to the clinic.

Assessors' recommendations:

It is highly recommended that the delivery of the COVID-19 negative PCR test result is confirmed before the admission of the patient in order to avoid gaps and, moreover, to prevent any contamination for the hospitalized patients of the clinic as well as for its staff.

PCC 2.2

Patients are encouraged to arrive alone to their appointment, except for instances where the patient requires the assistance of another individual (e.g., pediatric patients, people with special needs, elderly patients, etc.). If companions are allowed for patients receiving treatment, they should also be screened for signs and symptoms of COVID- 19 during patient check-in and should not be allowed entry into the facility if signs and symptoms are present. Companions should not be allowed if perceived to be at a high risk of contracting COVID-19 (e.g., having a pre-existing medically compromised condition). Any person accompanying a patient should be prohibited from entering the treatment area.

Temos rating: met

Assessors' findings:

Due to the condition of the patients, most of the times they are accompanied. For this reason it is asked that they provide a COVID-19 negative PCR test result.

Assessors' demands: See Demand PCC 2.1.

Assessors' recommendations:

It is highly recommended that the delivery of the COVID-19 negative PCR test result for the accompanying person is also confirmed before the admission of the patient.



- PCC 2.3 When collecting diagnostic respiratory specimens (e.g. nasopharyngeal or nasal swab) from a patient with possible SARS-CoV-2 infection, the following should occur:
 - 1. Specimen collection should be performed in a normal examination room with the door closed.
 - 2. Healthcare staff in the room should wear an N95 or equivalent or higher-level respirator (or facemask if a respirator is not available), eye protection, gloves, and a gown.
 - 3. Room surfaces are cleaned and disinfected promptly as described in the organization's hygiene and cleaning plan.

Temos rating: partially met

Assessors' findings:

It is mentioned in the related SOP 52 that an external cooperating laboratory doctor is responsible for the PCR sample collection and testing. It is not clarified whether sampling precautions are controlled, where the procedure takes place and if the cooperating doctor is obliged to conform with all standardized procedures and measures.

Assessors' demands:

Develop a standardized instruction for the process which is followed when a suspicious case needs to be tested. The collaborating laboratory has to provide the taken measures and the samples' transfer procedure to secure the testing results.

PCC 2.4 Communication with patients is respectful, polite and empathetic. This demeanor is assured by respective communication training, the use of a language that is understood by the patient, by speaking slowly and supported by written information, handouts, etc.

Temos rating: partially met

<u>Assessors' findings:</u> No sufficient evidence was provided.

Assessors' demands:

Provide respective pevidence abput how the staff is guided to communicate safety precautions to the patients and relatives/ accompanying persons satisfying the requested points of this standard.

PCC 2.5 Steps are taken to ensure everyone adheres to respiratory hygiene and cough etiquette, and hand hygiene, throughout the duration of the visit.

Temos rating: met

<u>Assessors' findings:</u> The provided material does not include references to the appropriate cough etiquette.

<u>Assessors' demands:</u> See demand for SIP 1.4.



Chapter 4 - Facility, Environmental and Technical Resources' Management (FET)

Temos rating: B (good achievement)

FET 1	Re-opening after temporary complete or partial closure of the organization						
FET 1.1	The organization follows the national guidelines for (re-)opening services as well as the instructions of the manufacturer regarding maintenance, calibration, cleaning, disinfection, and sterilization of devices and equipment in case the facilities have not been used due to a complete or partial closure.						
	Temos rating: not applicable						
	<u>Assessors' findings:</u> The clinic has not been closed during the lockdown periods in the country. This standard is considered as not applicable.						
FET 2	Access to the facility and patient placement Space within a healthcare facility is designed to allow for routine situations and mitigate the spread of infection through engineering controls that address a number of different patient needs. The built environment is not designed to accommodate many patients with comparable needs, as is necessary with this pandemic. It is important to examine these changing facility needs with the assistance of qualified facility management professionals that can assess the facility's engineering controls and patient flow and help verify that the organization's COVID-19 response will properly protect patients.						
FET 2.4	Inpatient treatment: where possible, patients are placed in single rooms. Temos rating: met						
	Assessors' recommendations: Please provide the isolation measures which are followed as part of the general clinic services' operations.						
FET 3	 Prevention of air and surface contamination by the use of sterilizers, disinfectant devices, and air purifiers - Additional engineering controls in very high and high exposure risk areas The organization applies effective room and air sterilization methods that prevent the spread of infectious agents throughout the hospital environment. It is recommended to consult a heating, ventilation and air conditioning (HVAC) professional to investigate increasing filtration efficiency to the highest level compatible with the HVAC system without significant deviation from designed airflow and to investigate the ability to safely increase the percentage of outdoor air supplied through the HVAC system (requires compatibility with equipment capacity and environmental conditions). Air purifying devices intended for medical purposes may be used in order to kill pathogens/microorganisms in the air by exposure to UV radiation or to remove them through filtration. Controlled ozone treatment may also apply for the disinfection of rooms and equipment. 						



FEI 3.1	Appropriate air-handling and decontamination systems are installed and maintained. These controls include but are not limited to the installation of high-efficiency air filters, air purifiers and sterilizers, increase/optimization of ventilation rates in the work environment and specialized negative pressure ventilation in some settings, such as for aerosol generating procedures (e.g. airborne infection isolation rooms, specialized autopsy suites in mortuary settings).
	Consider the addition of portable solutions (e.g. portable HEPA filtration units) to augment air quality in areas when permanent air-handling systems are not a feasible option.
	To assure that ventilation does not automatically change, limit the use of demand- controlled ventilation (triggered by temperature setpoint and/or by occupancy controls) during occupied hours and when feasible, up to two hours post occupancy.
	Temos rating: not applicable
	<u>Assessors' findings:</u> Aerosol-generating procedures do not take place in the clinic. The services are considered as low-risk for air contamination. This standard is evaluated as not applicable.
FET 3.2	Inpatients: Where available, patients with known or suspected COVID-19 are placed in an airborne infection isolation room (AIIR). If AIIRs are limited, patients are to be placed in a single room with the door closed and with a dedicated bathroom.
	Temos rating: met
	<u>Assessors' findings:</u> The isolation precautions are not explicitly described in the submitted SOPs.
	<u>Assessors' demands:</u> Provide the isolation measures which are followed as part of the general clinic services' operations.
FET 3.3	Inpatients: Airborne infection isolation rooms (AIIR) are used for performing aerosol- generating procedures with known or suspected COVID-19 patients.
	Temos rating: not applicable
	<u>Assessors' findings:</u> Aerosol-generating procedures do not take place in the clinic. The services are considered as low-risk for air contamination. This standard is evaluated as not applicable.
FET 3.4	Autopsy suites or other similar isolation facilities are used for postmortem activities when performing aerosol-generating procedures on the bodies of people who are known to have or suspected of having, COVID-19 at the time of their death.
	Temos rating: not applicable
FET 3.5	When handling specimens from known or suspected COVID-19 patients, precautions associated with Biosafety Level 2 are used for routine diagnostic testing. Procedures with a high likelihood of generating aerosols or droplets, should be done using



either a certified Class II Biological Safety Cabinet (BSC) or additional precautions to provide a barrier between the specimen and personnel. Site- and activity-specific biosafety risk assessments should be performed to determine if additional biosafety precautions are warranted based on situational needs.

Explanatory note:

The Centers for Disease Control differentiate between four biosafety levels (BSL) for laboratories.

- 1. BSL 1 is suitable for work involving well-characterized agents not known to consistently cause disease in immunocompetent adult humans, and present minimal potential hazard to laboratory personnel and the environment.
- 2. BSL 2 is suitable for work involving agents that pose moderate hazards to personnel and the environment. It differs from BSL 1 in that: 1) laboratory personnel have specific training in handling pathogenic agents and are supervised by scientists competent in handling infectious agents and associated procedures; 2) access to the laboratory is restricted when work is being conducted; and 3) all procedures in which infectious aerosols or splashes may be created are conducted in biological safety cabinets or other physical containment equipment.
- 3. BSL 3 is applicable to clinical, diagnostic, teaching, research, or production facilities where work is performed with indigenous or exotic agents that may cause serious or potentially lethal disease through the inhalation route of exposure. Laboratory personnel must receive specific training in handling pathogenic and potentially lethal agents, and must be supervised by scientists competent in handling infectious agents and associated procedures. All procedures involving the manipulation of infectious materials must be conducted within biological safety cabinets or other physical containment devices. A BSL 3 laboratory has special engineering and design features.
- 4. BSL 4 is required for work with dangerous and exotic agents that pose a high individual risk of aerosol-transmitted laboratory infections and life-threatening disease that is frequently fatal, for which there are no vaccines or treatments, or a related agent with unknown risk of transmission. This biosafety level is not found in the general healthcare provider setting.

Temos rating: not applicable

FET 4 Supplies

FET 4.1 Adequate supplies of equipment, medication and consumables are ensured considering that there might be shortage of some supplies which requires supplies shortage management and the adaptation of the purchasing process.

Remark – Risk of infection through food (supplies): Despite the large scale of the pandemic, there has been no report of transmission of COVID-19 via consumption of food to date. There is no evidence that food poses a risk to public health in relation to COVID-19.

There is no evidence that contaminated packages, which have been exposed to different environmental conditions and temperatures, transmit the infection. Nonetheless, to address concerns that virus present on the skin might be able to transfer to the respiratory system (for example by touching the face), persons handling packaging, including consumers, should adhere to the guidance of public health authorities regarding good hygiene practices, including regular and effective hand-washing.



Temos rating: partially met

Assessors' findings:

There is no evidence that a specific amount of PPE is available in the clinic given the special conditions of the pandemic.

Assessors' demands:

Provide a standardized instruction to ensure availability of the essential types and quantity of PPEs or other essential supplies in the clinic.

Chapter 5 - Teleconsultation and Telemedicine Services (TTS)

Temos rating: Not applicable

TTS 1	General requirements
TTS 1.1	Physicians delivering teleconsultation services are appropriately licensed in the patient's location and work in compliance with local health regulations.
	Remark: Most jurisdictions worldwide hold that licensing rules and medical practice laws are based not on the location of the physician, but rather on the location of the patient at the time of the teleconsultation.
	Temos rating: not applicable
TTS 1.2	Personnel (doctors, nurses, diagnostic laboratory technicians, etc.) that make use of digital tools and platforms for the provision of telemedicine services are adequately trained and experienced on the particular type of services.
	Temos rating: not applicable
TTS 1.3	Patients are provided with a complete explanation of the benefits and risks of services delivered via teleconsultation, and give their consent to such care. Communication in a language understood by the patient should be ensured, and appropriate referral pathways must be determined when necessary.
	Temos rating: not applicable
 TTS 1.4	All telemedicine services - and in particular those involving cross-border transfer and storage of patient data – occur via safeguard valid data protection including a declaration of the patient's informed consent regarding the transfer of his/her medical data.
	Temos rating: not applicable
TTS 1.5	Transparency of the identity of the health professional providing the service is ensured. Temos rating: not applicable
TTS 1.6	In order to ensure quality and safety of the provided services, special workflows and standardized procedures describing the telemedicine service are available, determining duties and responsibilities of the involved healthcare professionals. The standard of care



	is seen in-person. If the physician cannot competently and confidently diagnose or treat the patient via tele- consultation, he/she refers the patient to an in-person examination before rendering a diagnosis or prescribing therapeutic treatment.
	Temos rating: not applicable
TTS 1.7	Telemedicine services are integrated and interoperable with secure Electronic Health Record (EHR) systems. Alternatively, a special database of used and monitored data ensures traceability and continuity of patient care.
	Temos rating: not applicable
TTS 1.8	Physicians are permitted to prescribe remotely to the patient, and in case of cross-border prescription have a detailed knowledge of local drug names, availability and prescribing regulations in the patient's country.
	Temos rating: not applicable
TTS 1.9	To balance liability issues, particularly in the cross-border care cases, professional liability insurance is extended to telemedicine incidents and offers sufficient coverage.
	Temos rating: not applicable

should not be compromised and should be equal to the effect in the case where a patient

The clinic does not offer telemedicine services. The chapter was rated as not applicable.

Chapter 6 - Crisis Communication (CCO)

Temos rating: B (good achievement)

CCO 2	Crisis Communication Plan The organization has implemented a crisis communication plan or similar process or procedure that includes but is not limited to:				
CCO 2.1					
	 A decision-making roadmap. The definition of responsibilities within the crisis team including a clearly defined team leader and communications leader as well as a backup for overall responsibility. In small organizations different positions may be covered by the same person(s). The definition of logistics including operations, communications, supplies and resources. Communication scripts and protocols. A notification process for staff, patients, and other relevant parties including family members and media. Regular review and practical drills at least one time per year. 				
	7. Post-crisis review and evaluation of each element to determine what worked well and what needs to be changed/improved/removed for a more effective response. Communication plans include how signs, phone trees, and other methods of communication are used to inform staff, family members, visitors, and other persons coming into the facility (e.g. consultants, sales and delivery people) about the status of				



COVID-19 in the facility. Reliable and sustainable primary and back-up communication systems (e.g. landlines, internet, mobile devices, pagers, satellite telephones, two-way radio equipment) are ensured as well as access to updated contact lists.

Temos rating: met

Assessors' findings:

The points of the standard are not explicitly documented.

Assessors' demands:

The crisis management plan has to be updated to meet all the requirements described in this standard. A focus should be set to the communication matters and needs which may arise amidst a crisis.



Progress report and measures, next Temos International re-certification

Temos requires the completion of a Progress Report within 3 months of award outlining how you have addressed the demands and recommendations in the report and other improvements proposed.

The next Temos International **re-certification** is due in **February 2023**. In between a follow-up will take place on an annual basis by means of a questionnaire.

Please get in contact with Temos International for any important information you wish to transfer in the meantime. Temos looks forward to hearing from you.

With best regards

Prof. Dr. Rupert Gerzer Temos International Medical Board