	GENERAL TERMS OF BUSINESS VL-PRZ-07/03	Page:	1
		Pages:	1 / 8

No: VL-PRZ-07/03-01/2026

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GENERAL TERMS OF BUSINESS

The general terms of business apply to the verification/inspection/control of measuring instruments within the inspection body **Verification Laboratory „Verlab“ Ltd. (Ferhadija 27, 71 000 Sarajevo, Bosnia and Hercegowina).**

I INTRODUCTION

1.1. The General Rules of Inspection/Verification (the Rules) define the general provisions governing inspections within the activities of the Inspection Body (IB) Verlab and relate to the inspection of medical devices with a measuring function, carried out in accordance with the Law on Metrology of Bosnia and Herzegovina (“Official Gazette of B&H”No 19/01).

1.2 The Client and Verlab establish a business relationship based on an offer–purchase order or a contract for the performance of inspection activities (the Contract), whereby these Rules form an integral part of the offer and the Contract. If there are any deviations from these Rules in any part, the Contract must explicitly specify the provisions of the Rules from which deviations are made.


1.3 All amendments to the Contract shall be valid only if made in writing and signed by the Client and the inspection body or their authorized representatives.

1.4 Based on the Contract, the Client accepts that it does not expect any benefits or guarantees other than those explicitly stated in the Contract. All conditions that the Client normally applies within its management system, and which are not partially or fully compliant with these Rules, shall have no effect on the Contract unless they are expressly accepted by the inspection body in writing.

1.5 approaches each client in the same manner, without any restrictive conditions or discrimination.

II SERVICES

2.1 Verlab performs inspection/verification of medical devices with a measuring function for which it holds Accreditation Certificate No. IN-123-01 issued by the Institute for Accreditation of Bosnia and Herzegovina (BATA), in accordance with the requirements of the international standard BAS EN ISO/IEC 17020:2013 for a Type A inspection body.

	GENERAL TERMS OF BUSINESS VL-PRZ-07/03	Page:	2
		Pages:	2 / 8

2.2 Inspection/verification of medical devices with a measuring function is carried out in accordance with the Regulations (Section 9) on metrological and technical requirements for defibrillators, dialysis devices, electrocardiographs, infusion pumps and perfusors, incubators for neonatal and pediatric patients, patient monitors, ventilators and anesthesia machines, therapeutic ultrasound devices, and blood pressure measuring instruments.

2.3 The inspection body performs inspection/verification of the following devices: a) defibrillators, b) dialysis devices, c) electrocardiographs, d) infusion pumps and perfusors, e) incubators for neonatal and pediatric patients, f) patient monitors, g) ventilators and anesthesia machines, h) therapeutic ultrasound devices, and j) blood pressure measuring instruments.

2.4 Inspection/verification is carried out in accordance with the regulations referred to in Section IX and the documented procedures referred to in Section XX.

III INSPECTION PROCESS


3.1 Request for Inspection/Verification

As a request for inspection/verification, the client submits a duly completed official inspection request in writing using form VL-PRZ-07/02 *Service Request / Purchase Order*, containing: a) the name of the institution, ID/VAT number, address, and contact details (contact person, telephone); b) general information about the device subject to inspection: device name, model/manufacturer; c) quantity; d) the responsible person and the institution's official stamp.

The Client and the Inspection Body may hold a meeting for the purpose of defining all requirements related to the inspection. The Inspection Body shall inform the Client if the subject of the request is incomplete or outside the scope of activities of the inspection body Verlab.

3.2 Verification of Request Acceptability and Contracting

The Inspection Body (IB) makes the inspection request form available to all interested parties, either in writing or by e-mail. The request form may also be downloaded from the website <https://verlab.ba/> The IB may also accept requests that are not submitted on the official form, provided that such requests contain all the necessary information required to assess the scope of inspection and to prepare an offer and a Contract. The IB evaluates the acceptability of the request with regard to the description of the inspection object, the requested scope of inspection, acceptance criteria, location, deadlines, preparation requirements, available capacities, IB resources, and other relevant factors. If there are any ambiguities or deficiencies related to the request, lack of data, or missing documentation, the IB shall resolve these issues through contact with the applicant.

	GENERAL TERMS OF BUSINESS VL-PRZ-07/03	Page:	3
		Pages:	3 / 8

After verification of the request, the Inspection Body submits an offer to the Client. If the Client accepts the offer, this is followed by the conclusion of a contract and/or a purchase order/service request. After the contractual relationship has been established, the IB begins preparation and implementation of the inspection activities.

3.3 Inspection/Verification

Verlab independently or in cooperation with the Client prepares an inspection/verification plan in accordance with the provisions of the agreed normative documents: regulations, legislation, standards, technical specifications, etc.

3.4 Conformity Assessment

Inspection/verification of medical devices with a measuring function is carried out through conformity assessment in accordance with the requirements specified in the normative documents defined in Section 9.

3.5 Inspection Report


The final outcome of the inspection process is the issuance of an inspection report, a work order, and a certificate. Verlab prepares an inspection report containing information on the inspection location, the inspection object, and information on the inspection results for the specified measuring instrument.

IV RIGHTS AND OBLIGATIONS

4.1 Client Obligations

During the inspection process, the Client is obliged to:

- keep track of the expiry dates of verification/inspection,
- complete form VL-PRZ-07/02 Service Request / Purchase Order,
- submit a certified/signed request to the Inspection Body,
- conclude a Contract with the Inspection Body for inspection activities or issue a purchase order,
- provide comprehensive information about the object of inspection and the requirements it must meet
- ensure the availability of all reference documentation required for the inspection

	GENERAL TERMS OF BUSINESS VL-PRZ-07/03	Page:	4
		Pages:	4 / 8

- ensure that the object of inspection complies with the requirements of the applicable normative documents
- provide information on all deficiencies and any possible damage or malfunctions of the inspected object,
- ensure appropriate conditions for the performance of inspection activities with regard to occupational safety, the preparedness of the inspection object, its environment, and accessibility,
- use the inspection/verification report and certificate in a manner that does not harm the reputation of the Inspection Body,
- ensure that no inspection document is misused,
- comply with the provisions of the Contract,
- reimburse the Inspection Body for the actual inspection costs in the event of an incomplete or prematurely terminated inspection process.

4.2 Client Rights

The Client has the right to:


- be present during inspection activities,
- receive an inspection report, a work order, and an inspection certificate for each measuring instrument for which the inspection/verification process has been carried out.
- submit a complaint or appeal to Verlab regarding the inspection.

4.3 Obligations of the Inspection Body (Verlab)

4.3.1 Obligations of Verlab in the Inspection Process

The Inspection Body has the obligation to:

- act impartially in inspection/verification activities,
- protect the independence of inspection personnel,
- ensure the confidentiality of documents and information collected during inspection activities or obtained from other sources (e.g. legislators, complaints, etc.),
- disclose confidential information when required by law or based on contractual obligations,
- inform the Client in advance of the information it intends to disclose and make publicly available, unless prohibited by law,

	GENERAL TERMS OF BUSINESS VL-PRZ-07/03	Page:	5
		Pages:	5 / 8

- notify the Client of its intention to subcontract part of the inspection activities,
- ensure that all inspection activities are carried out in accordance with the Contract and internal inspection procedures,
- issue an inspection report, a work order, and an inspection certificate for each measuring instrument for which the inspection/verification process has been carried out.

4.3.2 Obligations of the IB in Case of Suspension or Withdrawal of the Status of a Designated Laboratory

In the event of suspension or withdrawal by the Institute for Metrology of Bosnia and Herzegovina (the Institute), the IB shall immediately cease its activities. IB Verlab shall resume activities within the scope of its designation only after the reasons for suspension have been resolved and written approval is obtained from the Institute.

If the IB has a concluded Contract for the provision of verification/inspection services with a Client that is currently in progress, it is obliged to inform the Client of these changes.

4.4 Rights of the Inspection Body (Verlab)


Verlab has the right to:

- receive from the Client the complete technical documentation describing the medical devices subject to inspection,
- verify the conditions for carrying out inspection activities with regard to occupational safety, the preparedness of the inspection object, its environment, and accessibility,
- prepare a report on the identified conditions for the inspection if these conditions are inadequate,
- postpone the inspection in case the conditions for carrying out the inspection are inadequate,
- proceed with the inspection once it determines that the conditions for carrying out the inspection are met,
- charge for all costs of inspection activities performed in the final inspection process.
- consider the Contract fulfilled after the issuance of the inspection/verification certificate.

V COMPLAINTS AND APPEALS

5.1 Opće odredbe

The policy of Verlab is to conduct its activities in accordance with defined rules and to the satisfaction of the Client and other interested parties, striving to prevent conditions that would give rise to complaints

	GENERAL TERMS OF BUSINESS VL-PRZ-07/03	Page:	6
		Pages:	6 / 8

or appeals during the implementation of procedures. However, if a complaint or appeal arises, it is addressed without delay.

The methods for submitting, receiving, handling, and resolving complaints and appeals are publicly available to Clients and other interested parties through these Rules. Upon request, the IB provides the procedure *VL-PR-12 Procedure for Handling Complaints and Appeals*. Complaints must be submitted exclusively in writing, generally using form *VL-PRZ-12/02 Complaint/Appeal*, which is published on the IB's website. The IB acknowledges receipt of the complaint/appeal and, whenever possible, informs the submitter in writing about the progress of its resolution and the final outcome. The IB will never act in a discriminatory manner toward the submitter of a complaint or appeal, nor toward the subject of the complaint or appeal, during the analysis, verification of justification, handling process, or until a decision is made. IB personnel who are in any way involved in the procedure that is the subject of a complaint or appeal do not participate in the analysis, preparation, review, or approval of the decision resolving the complaint or appeal. The IB is responsible for the entire process of resolving complaints and appeals, for making all decisions, and for collecting and verifying all information necessary to evaluate the complaint or appeal. Whenever possible, the submitter receives a formal notification upon the completion of the complaint resolution process.

5.2 Appeal


An appeal may relate to a certification decision resulting in the non-issuance of a certificate, to incorrect information on a certificate or other documentation arising from the inspection/verification process, to the scope of validity of the certificate being narrower or broader than agreed or expected, to decisions regarding temporary suspension or withdrawal of the certificate, and similar matters. Appeals must be submitted exclusively in writing to the IB (e-mail, fax, letter).

5.3 Complaint

A complaint is an expression of dissatisfaction to the IB, distinct from an appeal, made by a person or organization regarding IB activities, for which a response from the IB is expected. A complaint may relate to specific IB procedures during verification/inspection, such as interaction with IB personnel, deadlines, potential additional costs, and similar issues. Complaints must be submitted exclusively in writing to the IB (e-mail, fax, letter).

VI PUBLICITY AND DATA AVAILABILITY

These Rules are available to Clients and other interested parties via the website www.verlab.ba

	GENERAL TERMS OF BUSINESS VL-PRZ-07/03	Page:	7
		Pages:	7 / 8

Verlab maintains a record of all issued inspection reports, work orders, and inspection/verification certificates. All information regarding the Client, inspection reports, work orders, and certificates is considered confidential by Verlab and will not be disclosed to any third party without the explicit written consent of the Client, except in cases required by the laws of Bosnia and Herzegovina.

VII FEES AND PAYMENTS

The Client is obliged to pay Verlab for the inspection service performed after the issuance of the certificate, unless otherwise defined by the provisions of the Contract. Verification service fees are prescribed by the *Regulation on Amendments to the Regulation on the Amount and Method of Payment for the Services of the Institute for Metrology of BiH* ("Official Gazette of BiH" No. 75/14).

The IB may not charge for verification/inspection services below the fees specified in the above-mentioned Regulation but may additionally charge for any incurred costs, including transportation, accommodation of IB personnel, preparation of measuring instruments, etc.


VIII DISPUTES

All disputes between the contractual parties shall be attempted to be resolved amicably. If this is not possible, the competent court is the Municipal Court in Sarajevo.

IX NORMATIVE DOCUMENTS

The inspection/verification process is conducted in accordance with the following documents:

- a) Regulation on Metrological and Technical Requirements for Defibrillators (Official Gazette of BiH No. 75/14)
- b) Regulation on Metrological and Technical Requirements for Dialysis Devices (Official Gazette of BiH No. 75/14)
- c) Regulation on Metrological and Technical Requirements for Electrocardiographs (Official Gazette of BiH No. 75/14)
- d) Regulation on Metrological and Technical Requirements for Infusion Pumps and Perfusors (Official Gazette of BiH No. 75/14)
- e) Regulation on Metrological and Technical Requirements for Incubators for Neonatal and Pediatric Patients (Official Gazette of BiH No. 75/14)
- f) Regulation on Metrological and Technical Requirements for Patient Monitors (Official Gazette of BiH No. 75/14)
- g) Regulation on Metrological and Technical Requirements for Ventilators and Anesthesia Machines (Official Gazette of BiH No. 75/14)

	GENERAL TERMS OF BUSINESS VL-PRZ-07/03	Page:	8
		Pages:	8 / 8

- h) Regulation on Metrological and Technical Requirements for Therapeutic Ultrasound Devices (Official Gazette of BiH No. 75/14)
- i) Regulation on Metrological Conditions for Blood Pressure Measuring Instruments – Sphygmomanometers (Official Gazette of BiH No. 71/23)

X INSPECTION PROCEDURES

The inspection/verification process is conducted in accordance with the following documents:

- a) Working Procedure for Inspection of Defibrillators VL-RPR-02
- b) Working Procedure for Inspection of Dialysis Devices VL-RPR-03
- c) Working Procedure for Inspection of Infusion Pumps VL-RPR-04
- d) Working Procedure for Inspection of Perfusors VL-RPR-05
- e) Working Procedure for Inspection of Therapeutic Ultrasound Devices VL-RPR-06
- f) Working Procedure for Inspection of ECG Devices VL-RPR-07
- g) Working Procedure for Inspection of Patient Monitors VL-RPR-08
- h) Working Procedure for Inspection of Ventilators VL-RPR-09
- i) Working Procedure for Inspection of Anesthesia Machines VL-RPR-10
- j) Working Procedure for Inspection of Neonatal and Pediatric Incubators VL-RPR-11
- k) Working Procedure for Inspection of Blood Pressure Measuring Instruments VL-RPR-12
- l) Working Procedure for the Use of Software in Inspection VL-RPR-13
- m) Inspection Process Procedure VL-RPR-11

Director