



**Ministry of Health
Bhutan Food and Drug Authority
CERTIFICATION SERVICES**

**LEGALLY ENFORCEABLE AGREEMENT FOR FOOD PRODUCT
CERTIFICATION**

The Bhutan Food and Drug Authority (BFDA) operates Product Certification through **Certification Services** hereinafter referred to as the Certification Body makes agreement with the holder of the License,(Name and address of the Licensee) hereafter referred to as the Client for the certification of the product and schemes for which the details of the licenses are given below:

S.N	PRODUCT	SCHEME	STANDARD	TRADE NAME	CERTIFICATE NO.	CERTIFICATION DATE

In order to hold and use the licence, the client shall comply with the conditions of the agreement as follows:

Article 1: Regulations for certification and inspection

The stipulations of the general provisions for the certification system apply to this agreement specified in the Food Act of Bhutan, 2005, Food Rules and Regulations of Bhutan 2017 and also scheme requirements stipulated in ISO/IEC 17065.

Article 2: Rights and obligations of licensee

2.1 The holder of the licence, Client agrees that the certified products manufactured and supplied by him/her as specified in the licence to this agreement complies with the requirements stated by the CB in the identified product standard, Certification Scheme and certification requirements conditions.

2.2 The CB authorizes the Client to use the Bhutan Certification Mark on the products to which the licence applies and to announce publicly that certification has been received. The Client is liable to penal provisions under the Food Act of Bhutan, 2005 & Regulation in the event of misuse of the standards mark.

2.3 The Client agrees that the persons representing the CB will have unobstructed access without prior notification to the premises of the factory covered by the license during the normal working hours of the factory involved. The client also agrees to allow observers and trainee auditors with the technical audit team and observers or assessors from accreditation and regulatory bodies.

Doc. No.: BFDA-CS-PR4.1-01-FM-01	ISSUE NO.: 07	Approved by: MR	Page 1 of 6
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**Ministry of Health
Bhutan Food and Drug Authority
CERTIFICATION SERVICES**

2.4 The Client agrees that the products for which the licence is granted will be produced to the same specifications as the sample that has been submitted to the CB (as specified in the application form for product certification).

2.5 The Client agrees to apply the mark on the product labels that has been registered with the CB and makes claims regarding certification consistent with the scope of certification.

2.6 The Client agrees to inform the CB without delay the changes that affect its ability to conform to the requirements of the standards or certification requirements.

2.7 The Client agrees not use its product certification in such a manner as to bring the CB into disrepute and does not make any statement regarding its product certification that the CB may consider misleading or unauthorized;

2.8 If Client provides copies of the certification documents to others, the documents shall be reproduced in their entirety or as specified in the certification scheme;

2.9 The products for which the license is granted shall be manufactured and delivered in accordance with product standards and control measures specified in the latest Scheme of Testing and Inspections (STI), which may be revised from time to time.

2.10 During the period of suspension, the Client agrees to not make misleading claims and to advise relevant existing and potential purchasers regarding the status of certification, and cease to use the certification mark on the products manufactured since the date of notification of suspension.

2.11 The Client agrees for its manufacturing unit to have procedures in place to ensure that a non-conforming certified product that gave rise to suspension of certification is recalled.

Article 3: Surveillance

3.1 The CB carries out surveillance on the holder of the certification to determine continuing conformity to the standard during the period of validity of license.

3.2 The surveillance is carried out by the staff of the CB.

3.3 The testing of the samples taken from factory or market is carried out at least once a year or as required by sample failures or consumer complaints.

Article 4: Information on modifications in production

4.1 The client agrees to inform the CB, without delay, of the following changes that may affect its ability to conform to the certification requirements:

- any intended modification in the product, the process design or the manufacturing/production method or the quality management system
- any organizational and management changes (key managerial, decision-making or technical staff) which could affect the licensee's ability to continue to produce the certified product.

Doc. No.: BFDA-CS-PR4.1-01-FM-01	ISSUE NO.: 07	Approved by: MR	Page 2 of 6
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**Ministry of Health
Bhutan Food and Drug Authority
CERTIFICATION SERVICES**

- changes relating to legal, commercial, organizational status or ownership
- Major changes in outsourcing, manufacturing/testing equipment
- Change of contact address and production sites, premises
- Major changes in internal control measures
- Any other information indicating that the product may no longer comply with the requirements of the product standard and the certification Marks.

4.2 The Client agrees for any verification of the above changes by the CB as and when necessary.

4.3 The Client agrees to inform BFDA-CS in case they decide to outsource parts of production/processing activities to other producers. In case of outsourcing, the certified client is fully responsible for overseeing the compliance of outsourced activities as per the certification Standard.

4.4 The Client agrees to apply to the CB if it wishes to extend the scope of certification to additional types or models of products, to the same specified requirements as the products for which a certification is already granted.

4.5 The Client agrees to apply to the CB if it wishes to apply the certification to additional types of products, but to different specified requirements, or if the client wishes to apply for an extension of the certification to cover an additional facility that is not covered by the earlier licence.

Article 5: Complaints

The Client agrees to keep a record of complaints and action taken of any complaints regarding those aspects of the products covered by the licence and to report to the CB upon request for verification.

Article 6: Publicity

6.1 The Client has the right to publish that it has been authorized to mark the products to which the licence applies.

6.2 The CB uses its official website for placing information in the public domain, about the Client, the certified product, and the status of the license for use of marks of conformity, including updates on any cancellation or suspension of the license.

Article 7: Confidentiality

7.1. The CB ensures that confidentiality is maintained by all personnel involved on its behalf concerning all confidential information with which they become acquainted as a result of their contacts with the Client.

7.2. The CB ensures that Information about the client obtained from sources other than the client such as complainant, regulators during the process of certification, is treated as confidential.

Doc. No.: BFDA-CS-PR4.1-01-FM-01	ISSUE NO.: 07	Approved by: MR	Page 3 of 6
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**Ministry of Health
Bhutan Food and Drug Authority
CERTIFICATION SERVICES**

7.3 When the CB is required by Bhutan Civil Services Rules or authorized by contractual arrangements to release confidential information, the client or person concerned is, unless prohibited by law, notified of the information provided.

Article 8: Payment

The Client agrees to pay to the CB for all expenses in relation to the certification/ the surveillance, including sampling, test, assessment and administration costs. Payment becomes due within 30 days from the date of invoices. However, the certification services are currently provided free of cost by the Royal Government of Bhutan.

Article 9: Agreement period

9.1 This agreement comes into force on and remains in force until unless withdrawn for justified reasons or cancelled by either party upon due notice given to the other party.

9.2 The validity of the license is for three years period unless it is renewed or is suspended or revoked.

9.3 When the Client ceases its operation, it shall notify the CB in writing within thirty days from the date of cessation thereof.

Article 10: Termination of license

10.1 Depending on the reason for the Termination the following schedule of notice will be followed:

S.N	Situation requiring notice that can lead to Termination	Days of notice prior to Termination
1.	Manufacturers wish to terminate	Max. 60 days
2.	CB determines that the product is hazardous	Max. 60 days
3.	Violation of the standard requirements	Max. 60 days
4.	Non-payment of fees according to article 8	Max. 30 days
5.	Failure to meet other provisions of the agreement	Max. 60 days
6.	Mandatory compliance with new requirements in relation to revision of standards	Max. 60 days

10.2 Upon termination, suspension or withdrawal of certification, the holder agrees to discontinue use of standard mark on the product and in advertisement/publicity material including letter heads.

10.3 Advice of cancellation shall be sent by registered letter (or equivalent means) to the other party, stating the reasons and the date of Termination of the certification.



**Ministry of Health
Bhutan Food and Drug Authority
CERTIFICATION SERVICES**

Article 11: Changes to product requirements

11.1 The CB shall inform the Client of changes to product requirements and to specify the date by which changes will become effective; also to advise the licensee of any need for a supplementary examination of the products which are subject to this agreement.

11.2 Within a specified period of time after receipt of the advice described in paragraph.11.1, the Client shall inform CB whether he/she is prepared to accept the changes. If the Client gives confirmation within the specified period of his acceptance of the changes and provided the result of any supplementary examination is favourable, a supplementary licence will be issued or other modifications of the CB records.

11.3 If the Client advises the CB that he is not prepared to accept the modification within the time specified in accordance with 11.2 or if he/she allows the terms for acceptance to lapse, or if the result of any supplementary examination is not favourable, the licence covering the particular product shall cease to be valid on the date on which the modified specifications become effective, unless otherwise decided by the CB.

Article 12: Liability

12.1 The client has the primary responsibility to produce, process and supply products as per the Standard and certification requirements and they are liable for any non-conforming product.

12.2 All parties shall be bound by the legal requirements of Bhutan.

Article 13: Appeals/complaints

All appeals and complaints that may arise in connection with this agreement are first directed to the CB to be settled in accordance with the appeal and complaints procedures of BFDA.

Issued in duplicate and signed by an authorized representative of the Client and the Bhutan Food and Drug Authority– Certification Services.

For the Certification Client

For BFDA-CS

Name of the Client:

Address:

Jumey Lam (Near Tashichhodzong),

Address of the Client:

Thimphu, Bhutan

Signed:

Signed:

Doc. No.: BFDA-CS-PR4.1-01-FM-01	ISSUE NO.: 07	Approved by: MR	Page 5 of 6
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Ministry of Health
Bhutan Food and Drug Authority
CERTIFICATION SERVICES

Designation:

Name:

Date:

Designation:

Certification Manager/Management Representative

Name:

Date: