TEFANESO SERVICE

UNDER THE AUTORITY OF TEFANESO SWITZERLAND S. A.

Medical

3PLY PROTECTIVE

MEDICAL FACE MASKS

CE and FDA certified

MEDICAL DISPOSABLE FACE MASK

- Latex-free and hypo-allergenic
- Pleated with ear loops
- Bacterial Filteration Efficiency up to ≥98%
- Low breathing resistance
- 3-ply construction
- Soft inner surface for comfort
- Adjustable nose clip

APPLICATIONS

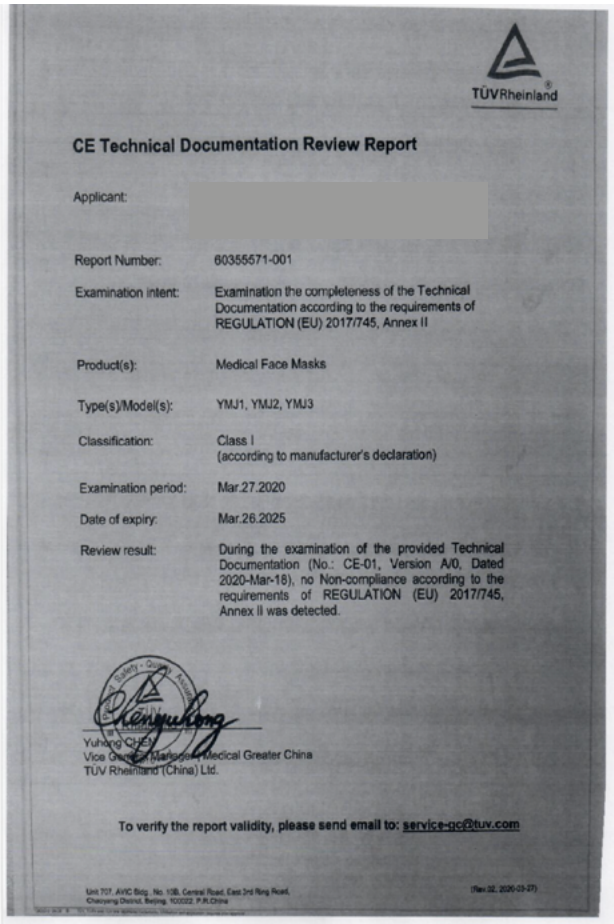
- Medical
- Industrial

Ref	110-010	Lev. I	
	110-011	Lev. I	(sterile)
	120-010	Lev. II	
	120-011	Lev. II	(sterile)
	130-010	Lev. IIR	
	130-011	Lev. IIR	(sterile)

TEFANESO SERVICE
Chemin de la Colline 7, 1863, Le Sépey Switzerland.
www.service.tefaneso.com / info@tefaneso.com
IDE: CHE-274.734.952

EN 14683:2019+AC:2019

	110-010 110-011	120-010 120-011	130-010 130-011
Bacterial filtration efficiency (BFE) (%)	≥95	≥98	≥98
Differential pressure for each test area (Pa/cm2)	<29,4	<29,4	<49,0
Spray resistance pressure (kPa)	N/A	N/A	≥16,0
Total bioburden per individual mask (CFU/g)	≤30	≤30	≤30



TÜVRheinland

CE Technical Documentation Review Report

Applicant:

Report Number: 60355571-001

Examination intent: Examination the completeness of the Technical Documentation according to the requirements of REGULATION (EU) 2017/745, Annex II

Product(s): Medical Face Masks

Type(s)/Model(s): YMJ1, YMJ2, YMJ3

Classification: Class I (according to manufacturer's declaration)

Examination period: Mar.27.2020

Date of expiry: Mar.26.2025

Review result: During the examination of the provided Technical Documentation (No.: CE-01, Version A/0, Dated 2020-Mar-16), no Non-compliance according to the requirements of REGULATION (EU) 2017/745, Annex II was detected.

Yuhong CHEN
Vice General Manager, Medical Greater China
TÜV Rheinland (China) Ltd.

To verify the report validity, please send email to: service-gc@tuv.com

FDA

Fiscal Year 2020

CERTIFICATE OF FDA REGISTRATION

This certifies that:

DUNS Number:

has completed the FDA Establishment Registration and Device Listing with the US Food & Drug Administration, through UCL-REG SERVICE INC.

Owner/Operator Number: 10065649

Listing No.	Product Code:	Device Name:
D381918	QKR	Face mask (except N95 respirator) for general public/healthcare personnel per IIE guidance Single-use medical face mask (non sterile) Medical isolation mask(non sterile)

UCL-REG SERVICE INC. will confirm that such registration remains effective upon request and presentation of this certificate until the end of the calendar year stated above, unless said registration is terminated after issuance of this certificate. UCL-REG SERVICE INC. makes no other representations or warranties, nor does this certificate make any representations or warranties to any person or entity other than the named certificate holder, for whose sole benefit it is issued. This certificate does not denote endorsement or approval of the certificate-holder's device or establishment by the U.S. Food and Drug Administration. UCL-REG SERVICE INC. assumes no liability to any person or entity in connection with the foregoing.

Pursuant to 21 CFR 807.39, " Registration of a device establishment or assignment of a registration number does not in any way denote approval of the establishment or its products. Any representation that creates an impression of official approval because of registration or possession of a registration number is misleading and constitutes misbranding."

The U.S.Food and Drug Administration does not issue a certificate of registration, nor does the U.S Food and Drug Administration recognize a certificate of registration. UCL-REG SERVICE INC. is not affiliated with the U.S. Food and Drug Administration.

UCL-REGSERVICE INC.
602 ROCKWOOD ROAD,WILMINGTON,
NEW CASTLE DE 19802 USA

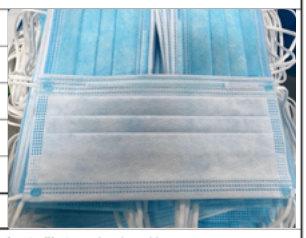
Cert. No.: M20750
Issued Date: 30 March 2020
Expiration Date: 31 December 2020

Produkte
Products

TÜVRheinland®

Prüfbericht-Nr.: *Test Report No.:*	**60358336 001**	**Auftrags-Nr.:** *Order No.:*	**190105940**	Seite 1 von 14 *Page 1 of 14*
Kunden-Referenz-Nr.: *Client Reference No.:*	**N/A**	**Auftragsdatum:** *Order date:*	**2019-11-29**	

Prüfgegenstand: *Test item:*	**Medical Face Masks**
Bezeichnung / Typ-Nr.: *Identification / Type No.:*	**YMJ1, YMJ2**
Auftrags-Inhalt: *Order content:*	**Type test**
Prüfgrundlage: *Test specification:*	**EN 14683:2019+AC:2019**
Wareneingangsdatum: *Date of receipt:*	**2020-03-23**
Prüfmuster-Nr.: *Test sample No.:*	**Engineering sample**
Prüfzeitraum: *Testing period:*	**2020-03-23 to 2020-03-31**
Ort der Prüfung: *Place of testing:*	**TÜV Rheinland (China) Ltd.**
Prüflaboratorium: *Testing laboratory:*	**TÜV Rheinland (China) Ltd.**
Prüfergebnis*: *Test result*:*	**Pass**



geprüft von / *tested by:* Han Dong

Datum / *Date*	Name / Stellung / *Name / Position*	Unterschrift / *Signature*
2020-04-08	Han Dong / Project Engineer	

kontrolliert von / *reviewed by:* Chen Yuhong

Datum / *Date*	Name / Stellung / *Name / Position*	Unterschrift / *Signature*
2020-04-08	Chen Yuhong / Reviewer	

Sonstiges / *Other:*

- Attachment 1. Photographic Documentation (3 pages)

Zustand des Prüfgegenstandes bei Anlieferung: Prüfmuster vollständig und unbeschädigt
Condition of the test item at delivery: *Test item complete and undamaged*

* Legende:	1 = sehr gut	2 = gut	3 = befriedigend	4 = ausreichend	5 = mangelhaft
	P(ass) = entspricht o.g. Prüfgrundlage(n)		F(ail) = entspricht nicht o.g. Prüfgrundlage(n)	N/A = nicht anwendbar	N/T = nicht getestet
Legend:	*1 = very good*	*2 = good*	*3 = satisfactory*	*4 = sufficient*	*5 = poor*
	P(ass) = passed a.m. test specification(s)		*F(ail) = failed a.m. test specification(s)*	*N/A = not applicable*	*N/T = not tested*

Dieser Prüfbericht bezieht sich nur auf das o.g. Prüfmuster und darf ohne Genehmigung der Prüfstelle nicht auszugsweise vervielfältigt werden. Dieser Bericht berechtigt nicht zur Verwendung eines Prüfzeichens.

This test report only relates to the a. m. test sample. Without permission of the test center this test report is not permitted to be duplicated in extracts. This test report does not entitle to carry any test mark.

VDH TUV Rheinland(China) Ltd. Room 303,1st Area Chuang Xin Building No.8,No.12,Hong Da Road (north) Economic Technological Development Area Beijing 100176 P.R.China

EN 14683:2019+AC: 2019
Medical face masks -
Requirements and test methods

Report Reference No. ..... :	**60358336 001**
Date of issue..... :	See cover page
Total number of pages ..... :	See cover page
Testing Laboratory ..... :	**TÜV Rheinland (China) Ltd.**
Address..... :	Unit 707, AVIC Building, No. 10B, Central Road, East 3rd Ring Road, Chaoyang District, Beijing 100022, P. R. China
Test specification:	
Standard ..... :	**EN 14683:2019+AC:2019**
Test procedure..... :	Type test
Non-standard test method..... :	N/A
Test Report Form No. ..... :	EN 14683:2019+AC:2019
Test Report Form Originator ..... :	TÜV Rh (SZ)
Master TRF ..... :	2020-03
Test item description..... :	**Medical Face Masks**
Trade Mark..... :	N/A
Model/Type reference..... :	**YMJ1, YMJ2**
Classification..... :	Type II for YMJ1 and YMJ2

List of Attachments (including a total number of pages in each attachment):

- Attachment 1. Photos documentation (3 pages).

Summary of testing:

Tests performed (name of test and test clause):

Clause 5.2.2: Bacterial filtration efficiency (BFE);

Clause 5.2.3: Breathability

Clause 5.2.4: Splash resistance

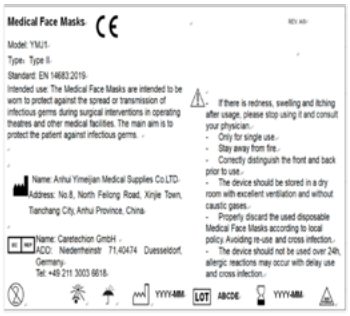
Clause 5.2.5: Microbial cleanliness (Bioburden).

Note: All tests listed as above have been conducted in the competent external lab under the supervision of a TUV engineer

Copy of marking plate

The artwork below may be only a draft.

Label for YMJ1



Label for YMJ2

Testing

Date of receipt of test item(s): **2020-03-23**

Dates of tests performed: **2020-03-23 to 2020-03-31**

Possible test case verdicts:

- test case does not apply to the test object: N/A
- test object does meet the requirement: P (Pass)
- test object was not evaluated for the requirement: N/E (collateral standards only)
- test object does not meet the requirement: F (Fail)

General remarks:

"(See Attachment #)" refers to additional information appended to the report.
"(See appended table)" refers to a table appended to the report.
The tests results presented in this report relate only to the object tested.
This report shall not be reproduced except in full without the written approval of the testing laboratory.
List of test equipment must be kept on file and available for review.
Additional test data and/or information provided in the attachments to this report.

Throughout this report a ☐ comma / ☒ point is used as the decimal separator.

General product information:

Intended use for Type II:
The Medical Face Masks (Model: YMJ1 and YMJ2) are intended to be worn to protect against the spread or transmission of infectious germs during surgical interventions in operating theatres and other medical facilities. The main aim is to protect the patient against infectious germs.

Intended use for Type IIR:
The Medical Face Masks (Model: YMJ3) is intended to be worn to protect against the spread or transmission of infectious germs during surgical interventions in operating theatres and other medical facilities. The main aim is to protect the patient against infectious germs. In addition, in certain situations the wearer should be protected against splashes of potentially contaminated liquids and viable particles.

Model difference:
The YMJ1 and YMJ2 Medical Face Masks are Flat Pleated type mask, utilizing Ear Loops way for wearing, and they all have Nose Piece design for fitting the face mask around the nose.
The raw materials of the two models are polypropylene (PP) non-woven fabric, polypropylene (PP) melt-blown non-woven fabric and Elastic bands.
YMJ1 and YMJ2 share the same materials and same production process. The only difference between the two models is size. The size of YMJ2 is smaller than YMJ1. Therefore, the biocompatibility test results of YMJ2 can represent YMJ1.

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
4	**Classification**		P
	Medical face masks specified in this European Standard are classified into two types (Type I and Type II) according to bacterial filtration efficiency whereby Type II is further divided according to whether or not the mask is splash resistant.	Type II for YMJ1 and YMJ2	P
5	**Requirements**		P
5.1	**General**		P
5.1.1	**Materials and construction**		P
	The medical face mask is a medical device, generally composed of a filter layer that is placed, bonded or moulded between layers of fabric.	Complied	P
	The medical face mask shall not disintegrate, split or tear during intended use.	Complied	P
	In the selection of the filter and layer materials, attention shall be paid to cleanliness.	Complied	P
5.1.2	**Design**		P
	The medical face mask shall have a means by which it can be fitted closely over the nose, mouth and chin of the wearer and which ensures that the mask fits closely at the sides.	Complied	P
	Medical face masks may have different shapes and constructions as well as additional features such as a face shield (to protect the wearer against splashes and droplets) with or without anti-fog function, or a nose bridge (to enhance fit by conforming to the nose contours).	Complied	P
5.2	**Performance requirements**		P
5.2.1	**General**		P
	All tests shall be carried out on finished products or samples cut from finished products.		P
5.2.2	**Bacterial filtration efficiency (BFE)**		P
	When tested in accordance with Annex B, the BFE of the medical face mask shall conform to the minimum value given for the relevant type in Table 1.	The Bacterial Filtration Efficiency ≥ 98% See appended Table 5.2.2	P
	For thick and rigid masks such as rigid duckbill or cup masks the test method may not be suitable as a proper seal cannot be maintained in the cascade impactor. In these cases, another valid equivalent method shall be used to determine the BFE.	Not such masks	N/A
	When a mask consists of two or more areas with different characteristics or different layer-composition, each panel or area shall be tested individually.		N/A

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	The lowest performing panel or area shall determine the BFE value of the complete mask		N/A
5.2.3	**Breathability**		P
	When tested in accordance with Annex C, the differential pressure of the medical face mask shall conform to the value given for the relevant type in Table 1.	See appended Table 5.2.3	P
	If the use of a respiratory protective device as face mask is required in an operating theatre and/or other medical settings, it might not fulfil the performance requirements with regard to differential pressure as defined in this European Standard. In such case, the device should fulfil the requirement as specified in the relevant Personal Protective Equipment (PPE) standard(s).	No such respiratory protective device provided	N/A
5.2.4	**Splash resistance**		P
	When tested in accordance with ISO 22609:2004 the resistance of the medical face mask to penetration of splashes of liquid shall conform to the minimum value given for Type IIR in Table 1.		
5.2.5	**Microbial cleanliness (Bioburden)**		P
	When tested according to EN ISO 11737-1:2018 the bioburden of the medical mask shall be ≤ 30 CFU/g tested (see Table 1).	The bioburden of the medical mask was <30 CFU/g See appended Table 5.2.5	P
5.2.6	**Biocompatibility**		P
	According to the definition and classification in EN ISO 10993-1:2009, a medical face mask is a surface device with limited contact.	The biocompatibility of mask was evaluated in following report: CSTBR20030118 CSTBR20030119 CSTBR20030110 for YMJ1 and YMJ2	P
	The manufacturer shall complete the evaluation of the medical face mask according to EN ISO 10993-1:2009 and determine the applicable toxicology testing regime.	The biocompatibility of mask was evaluated in following report: CSTBR20030118 CSTBR20030119 CSTBR20030110 for YMJ1 and YMJ2	P

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict
	The results of testing should be documented according to the applicable parts of the EN ISO 10993 series.	The biocompatibility of mask was evaluated in following report: CSTBR20030118 CSTBR20030119 CSTBR20030110 for YMJ1 and YMJ2	P
	The test results shall be available upon request.	The biocompatibility of mask was evaluated in following report: CSTBR20030118 CSTBR20030119 CSTBR20030110 for YMJ1 and YMJ2	P
6	**Marking, labelling and packaging**		P
	Annex I, §13, of the Medical Devices Directive (93/42/EEC) or Annex I, §23, of the Medical Device Regulation (EU) 2017/745 specifies the information that should be specified on the packaging in which the medical face mask is supplied.	Considered Only use plastic transparent packaging, no any outer packaging used All information be specified on the label	P
	The following information shall be supplied:		P
	a) number of this European Standard;	EN 14683:2019	P
	b) type of mask (as indicated in Table 1).	Type II for YMJ1 and YMJ2	P
	EN ISO 15223-1:2016 and EN 1041:2008+A1:2013 should be considered.	Compliance	P

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IDE: CHE-274.734.952

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict

5.2.2	TABLE: Bacterial filtration efficiency (BFE)							P
Batch/ lot no.:	Test Speci -men no.:	Dimension of the test specimen L x W (mm x mm)	test area (cm^2)	Flow rate (l/min)	Mean of the total plate counts of the two positive controls	Mean plate count of the negative controls	BFE for each test specimen (%)	Remarks
YMJ1	1	100×100	100	28.3	2452	0	99	≥98
	2	100×100	100	28.3	2396	0	100	≥98
	3	100×100	100	28.3	2423	0	100	≥98
	4	100×100	100	28.3	2349	0	100	≥98
	5	100×100	100	28.3	2509	0	99	≥98
YMJ2	1	100×100	100	28.3	2372	0	100	≥98
	2	100×100	100	28.3	2353	0	100	≥98
	3	100×100	100	28.3	2536	0	100	≥98
	4	100×100	100	28.3	2353	0	100	≥98
	5	100×100	100	28.3	2412	0	100	≥98

Supplementary information:
1, Each specimen was conditioned at (21 ± 5)°C and (85 ± 5)% relative humidity for 4h to bring them into equilibrium with atmosphere prior to testing.
2, The side of the test specimen was facing towards the challenge aerosol:_____

EN 14683:2019+AC:2019			
Clause	Requirement + Test	Result - Remark	Verdict

5.2.3	TABLE: Breathability (Differential pressure)				P
Batch/ lot no.:	Test Specimen number-Test area number	Differential pressure for each test area (Pa/cm^2)	The averaged differential pressure for each test specimen (Pa/cm^2)	Flow rate (l/min)	Remarks
YMJ1	1-1	29.6	29.7	8	<40
	1-2	29.8		8	<40
	1-3	29.5		8	<40
	1-4	29.6		8	<40
	1-5	30.0		8	<40
	2-1	23.8	23.6	8	<40
	2-2	23.9		8	<40
	2-3	23.4		8	<40
	2-4	23.5		8	<40
	2-5	23.4		8	<40
	3-1	21.2	21.5	8	<40
	3-2	21.6		8	<40
	3-3	21.7		8	<40
	3-4	21.3		8	<40
	3-5	21.7		8	<40
	4-1	24.8	24.6	8	<40
	4-2	24.7		8	<40
	4-3	24.9		8	<40
	4-4	24.1		8	<40
	4-5	24.5		8	<40
	5-1	25.9	25.7	8	<40
	5-2	25.1		8	<40
	5-3	25.8		8	<40
	5-4	25.6		8	<40
	5-5	26.1		8	<40
YMJ2	1-1	27.6	27.3	8	<40
	1-2	27.2		8	<40
	1-3	27.5		8	<40

EN 14683:2019+AC:2019					
Clause	Requirement + Test		Result - Remark		Verdict
	1-4	27.3		8	<40
	1-5	26.9		8	<40
	2-1	28.7	28.5	8	<40
	2-2	28.9		8	<40
	2-3	28.3		8	<40
	2-4	28.2		8	<40
	2-5	28.4		8	<40
	3-1	27.9	27.8	8	<40
	3-2	27.6		8	<40
	3-3	27.6		8	<40
	3-4	28.1		8	<40
	3-5	27.8		8	<40
	4-1	29.6	29.2	8	<40
	4-2	29.2		8	<40
	4-3	29.5		8	<40
	4-4	28.9		8	<40
	4-5	28.8		8	<40
	5-1	28.6	28.7	8	<40
	5-2	28.9		8	<40
	5-3	28.7		8	<40
	5-4	28.5		8	<40
	5-5	28.8		8	<40

EN 14683:2019+AC:2019				
Clause	Requirement + Test	Result - Remark		Verdict
	30	Polypropylene melt-blown non-woven fabric	Pass	-
	31	Polypropylene melt-blown non-woven fabric	Pass	-
	32	Polypropylene melt-blown non-woven fabric	Pass	-

Supplementary information:
1, Each specimen was conditioned at 21±5°C and 85±10 % relative humidity for _4_h to bring them into equilibrium with atmosphere prior to testing.
2, The description of target area tested: outside
3, Any technique used to enhance visual detection of synthetic blood:_____
4, The temperature and relative humidity for testing: _23__ °C and _89__ %
5, Description of any pre-treatment techniques used:____

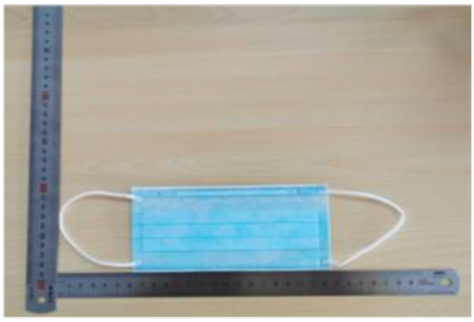
5.2.5	TABLE: Microbial cleanliness (Bioburden)				P
Batch/ lot no.:	Mask(under test) no.:	Weight of each mask (g)	Total bioburden per individual mask (CFU/g)	Remarks	
YMJ1	1	3.0	15.0	≤30	
	2	3.1	15.8	≤30	
	3	3.0	15.0	≤30	
	4	3.1	13.9	≤30	
	5	3.0	16.3	≤30	
YMJ2	1	3.0	15.0	≤30	
	2	3.1	15.8	≤30	
	3	3.0	15.0	≤30	
	4	3.1	13.9	≤30	
	5	3.0	16.3	≤30	

Supplementary information:
The plates are incubated for 3 days at 30 °C and 7 days at (20 to 25) °C for TSA and SDA plates respectively.

END OF TEST REPORT, CONTINUED AS ATTACHMENT 1

Photo Documentation
Report Number: 60358336 001 Attachment 1
Model: YMJ1, YMJ2

Pic.1: The obverse side view of YMJ1



Pic.2: The obverse side view of YMJ2

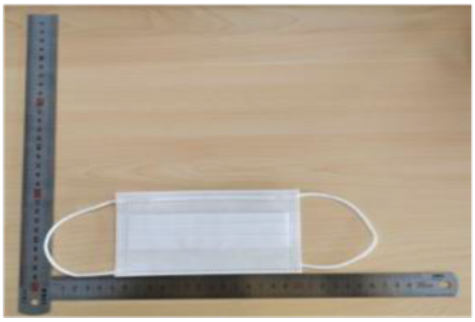


Photo Documentation
Report Number: 60358336 001 Attachment 1
Model: YMJ1, YMJ2

Marking, labelling and packaging of YMJ1

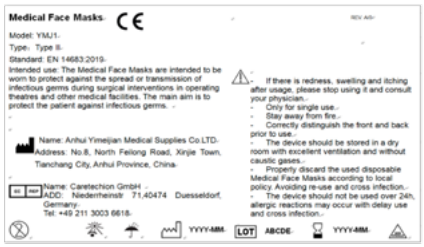


Photo Documentation
Report Number: 60358336 001 Attachment 1
Model: YMJ1, YMJ2

Marking, labelling and packaging of YMJ2

TEFANESO Services provide:

- Product sourcing,
- Quality control according to internal requirements,
- Order tracking,
- Support and assistance with customs and export formalities,
- Active search for solutions.

Our offices in Shanghai and Guangdong are located near the customs offices of these economic hubs. We are therefore able to intervene actively in the progress of customs formalities and procedures and thus help to speed up the finalization, if necessary.

TEFANESO Switzerland SA (hereinafter «Tefaneso») reserves the right to procure the product from supplier(s) different from the company indicated on the certificates mentioned in the appendix if such company cannot deliver the product. Tefaneso shall guarantee that the products from the other supplier(s) will scrupulously correspond to the product in terms of specifications, standards, tests and certifications.