Company: Trust Right Testing and Certification Service (Zhongshan) Ltd.
Address:No.601,Block 8,Hongji E Valley Industry Center,Nantou Town,Zhongshan City,P.R.China
Tel:0760-86117019

TL-861

Test Report

·Filtering half masks to protect against particles

PERFORMED IN ACCORDANCE WITH:

☒ EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking

Test Report No.: R20200049

Tested by (name + function + signature)….:	Alex He	Test Engineer
Approved by (name + function + signature)…:	Dyne Wang	Laboratory Manager
Date of issue :		Jun 12th, 2020

Project No.:	**P20200072**
Testing Laboratory .....:	**Trust Right Testing and Certification Service (Zhongshan) Ltd.**
Address .....:	No.28, Shangjian Road, Nantou Town, Zhongshan Guangdong
Testing Location.....:	**Trust Right Testing and Certification Service (Zhongshan) Ltd.**
Address .....:	No.28, Shangjian Road, Nantou Town, Zhongshan Guangdong
Applicant's name.....:	**UNIVERSAL CERTIFICATION and SURVEILLANCE SERVICES Trade Co.**
Address .....:	
Manufacturer's name .....:	**Wenzhou Leikang Medical Technology Co., Ltd**
Address .....:	Room 401, 4th floor, Building No.21, Wenzhou National University Science Park, No.89 Fengfang Rd. Economic Development Zone, Ouhai District, Wenzhou, Zhejiang Province, China
Factory's name .....:	**Same as manufacturer**
Address .....:	Same as manufacturer
Test item description:	**Filtering half mask**
Trade Mark .....:	N/A
Model/Type reference.....:	LK-008
Grade.....:	FFP2
Country of destination (code) .....:	N/A
Sample	
Samples received on .....:	June 3rd, 2020
Reference samples.....:	S202000LK
Samples tested on.....:	June 3rd, 2020 – Jun 12th, 2020
Result..... :	The test items PASSED/~~FAILED~~ partially the test specification(s). For detailed testing of items, please refer to the report and testing data.

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TL-861

Test Report

RELEASE CONTROL RECORD		
TEST REPORT NUMBER	**REASON OF CHANGE**	**DATE OF ISSUE**

Company: Trust Right Testing and Certification Service (Zhongshan) Ltd.
Address:No.601,Block 8,Hongji E Valley Industry Center,Nantou Town,Zhongshan City,P.R.China
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Test Report

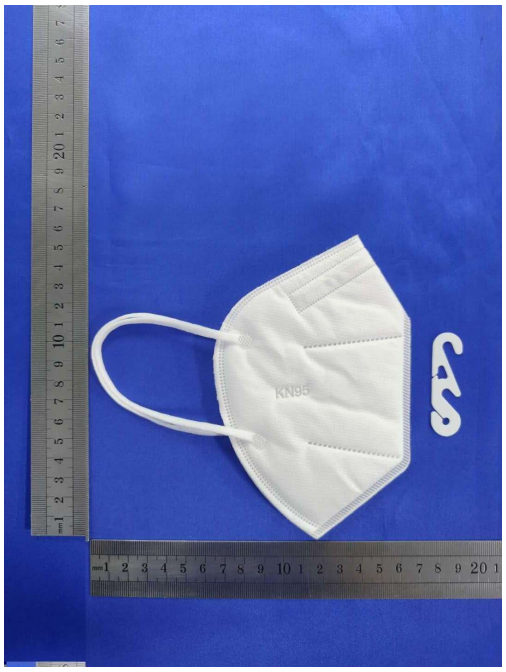
GENERAL DESCRIPTION OF THE APPLIANCE

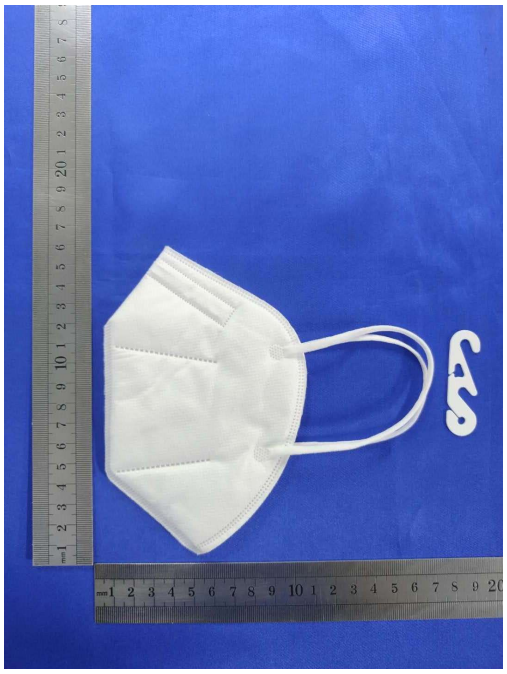
1, Description of the appliances

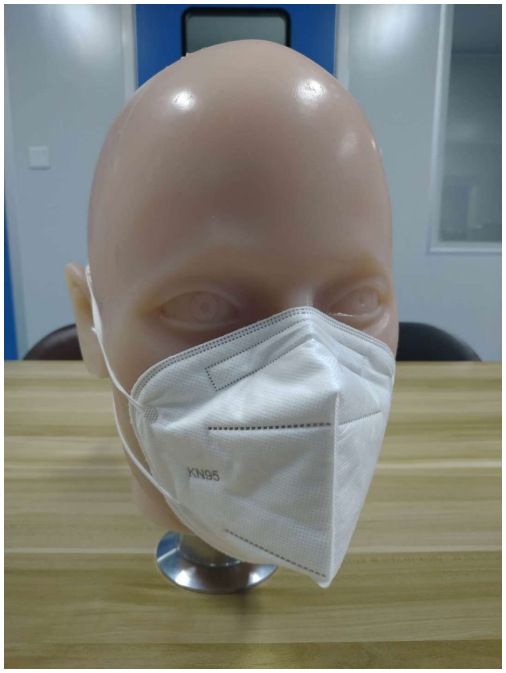
Product description	Filtering half mask
Product name	Filtering half mask
Model	LK-008
Classification	FFP2

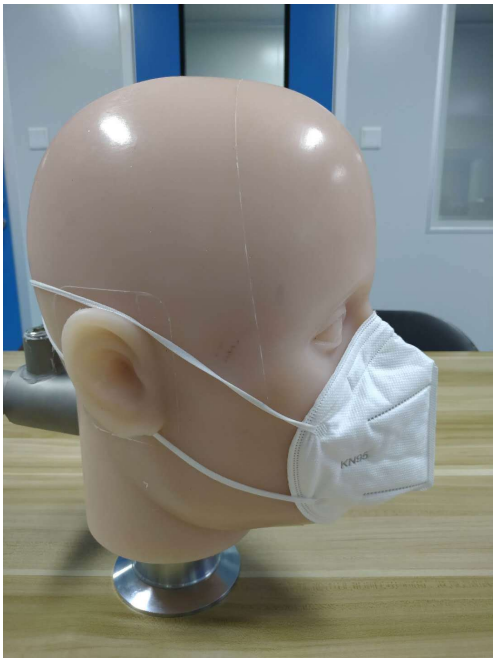
Test Report

PICTURES









PRINCIPALS COMPONENTS			
COMPONENT	MANUFACTURER	MODEL	Certificate/report

Test Report

Evaluation according to the test specification (standard)			
Abbreviations of the verdict: **P(ass) = passed** **F(ail) = failed** **N/A = not applicable** **N/T = not tested**			
EN 149:2001+A1:2009 Respiratory protective devices - Filtering half masks to protect against particles - Requirements, testing, marking			
Clause	Requirements	Result/Comment	Verdict
1	Scope		
2	Normative references		
3	Terms and definitions		
4	Description		
5	Classification		
	Particle filtering half masks are classified according to their filtering efficiency and their maximum total inward leakage. There are three classes of devices:		P
	- FFP1		N/A
	- FFP2	Designation is Grade FFP2.	P
	- FFP3		N/A
6	Designation		P
	Particle filtering half masks meeting the requirements of this European Standard shall be designated in the following manner:		
7	Requirements		P
7.1	General		P
	All test all test samples shall meet the requirements.		P
7.2	Nominal values and tolerances		P
	Except for temperature limits, values which are not stated as maxima or minima shall be subject to a tolerance of ± 5%. Unless otherwise specified, the ambient temperature for testing shall be(16-32)° C, and the temperature limits shall be subject to an accuracy of±1° C		P
7.3	Visual inspection		P
	The visual inspection shall also include the marking and the information supplied by the manufacturer.	In accordance with requirement	P

Test Report

7.4	Packaging		P
	Particle filtering half masks shall be offered for sale packaged in such a way that they are protected against mechanical damage and contamination before use.	In accordance with requirement	P
7.5	Material		P
	Materials used shall be suitable to withstand handling and wear over the period for which the particle filtering half mask is designed to be used. After undergoing the conditioning described in 8.3.1 none of the particle filtering half masks shall have suffered mechanical failure of the facepiece or straps. Three particle filtering half masks shall be tested. When conditioned in accordance with 8.3.1 and 8.3.2 the particle filtering half mask shall not collapse. Any material from the filter media released by the air flow through the filter shall not constitute a hazard or nuisance for the wearer.	No mechanical failure after undergoing the conditioning described in 8.3.1. No collapse when conditioned in accordance with 8.3.1 and 8.3.2.	P
7.6	Cleaning and disinfecting	Single shift use only.	N/A
7.7	Practical performance		P
	The particle filtering half mask shall undergo practical performance tests under realistic conditions. These general tests serve the purpose of checking the equipment for imperfections that cannot be determined by the tests described elsewhere in this standard. Where practical performance tests show the apparatus has imperfections related to wearer's acceptance, the test house shall provide full details of those parts of the practical performance tests which revealed these imperfections.	No imperfections.	P
7.8	Finish of parts		P
	Parts of the devices likely come into contact with the wearer shall have no sharp edges or burrs.	No sharp edges or burrs.	P

Test Report

7.9	Leakage		P
7.9.1	Total inward leakage		P
	The laboratory tests shall indicate that the particle filtering half mask can be used by the wearer to protect with high probability against the potential hazard to be expected. The total inward leakage consists of three components: face seal leakage, exhalation valve leakage (if exhalation valve fitted) and filter penetration. For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than 25 % for FFP1 11 % for FFP2 5 % for FFP3 and, in addition, at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than 22 % for FFP1 8 % for FFP2 2 % for FFP3 Testing shall be done in accordance with 8.5.	Meeting requirement of 11 % for FFP2 Meeting requirement of 8 % for FFP2 Detail refer to table 1	P
7.9.2	Penetration of filter material		P
	The penetration of the filter of the particle filtering half mask shall meet the requirements of Table 1. **Table 1 — Penetration of filter material** Classification | Maximum penetration of test aerosol: Sodium chloride test 95 l/min % max. | Paraffin oil test 95 l/min % max. FFP1 | 20 | 20 FFP2 | 6 | 6 FFP3 | 1 | 1 A total of 9 samples of particle filtering half masks shall be tested for each aerosol.	Detail refer to table 2	P
7.10	Compatibility with skin		P
	Materials that may come into contact with the wearer's skin shall not be known to be likely to cause irritation or any other adverse effect to health.	No irritation or any other adverse effect to health.	P
7.11	Flammability		P
	The material used shall not present a danger for the wearer and shall not be of highly flammable nature.	Detail refer to table 3	P

Test Report

<table>
<tr><td>7.12</td><td>Carbon dioxide content of the inhalation air</td><td></td><td>P</td></tr>
<tr><td></td><td>The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0% (by volume).</td><td>Detail refer to table 4</td><td>P</td></tr>
<tr><td>7.13</td><td>Head harness</td><td></td><td>P</td></tr>
<tr><td></td><td>Head harness shall be designed can be donned and removed easily and adjustable or self-adjusting and sufficiently robust to hold the particle.</td><td></td><td>P</td></tr>
<tr><td>7.14</td><td>Field of vision</td><td></td><td>P</td></tr>
<tr><td></td><td>Field of vision is acceptable in practical performance tests.</td><td></td><td>P</td></tr>
<tr><td>7.15</td><td colspan="3">Exhalation valve(s)</td></tr>
<tr><td></td><td>A particle filtering half mask may have one or more exhalation valve(s) and shall function correctly in all orientations.
If an exhalation valve is provided it shall be protected against or be resistant to dirt and mechanical damage and may be shrouded or may include any other device that may be necessary for the particle filtering half mask to comply with 7.9.
Exhalation valve(s), if fitted, shall continue to operate correctly after a continuous exhalation flow of 300 l/min over a period of 30 s.
When the exhalation valve housing is attached to the faceblank, it shall withstand axially a tensile force of 10 N applied for 10 s.</td><td>No exhalation valve</td><td>N/A</td></tr>
<tr><td>7.16</td><td>Breathing resistance</td><td></td><td>P</td></tr>
<tr><td></td><td>The breathing resistances apply to valved and valveless particle filtering half mask and shall meet the requirements of table 2.
Table 2 — Breathing resistance
<table>
<tr><td rowspan="3">Classification</td><td colspan="3">Maximum permitted resistance (mbar)</td></tr>
<tr><td colspan="2">inhalation</td><td>exhalation</td></tr>
<tr><td>30 l/min</td><td>95 l/min</td><td>160 l/min</td></tr>
<tr><td>FFP1</td><td>0,6</td><td>2,1</td><td>3,0</td></tr>
<tr><td>FFP2</td><td>0,7</td><td>2,4</td><td>3,0</td></tr>
<tr><td>FFP3</td><td>1,0</td><td>3,0</td><td>3,0</td></tr>
</table></td><td>Detail refer to table 5</td><td>P</td></tr>
<tr><td>7.17</td><td>Clogging</td><td></td><td>N/A</td></tr>
<tr><td>7.18</td><td>Demount-able parts</td><td></td><td>N/A</td></tr>
<tr><td>8</td><td colspan="3">Testing</td></tr>
<tr><td>9</td><td colspan="3">Marking</td></tr>
<tr><td>9.1</td><td colspan="3">Packaging</td></tr>
<tr><td></td><td colspan="3">The following information shall be clearly and durably marked on the smallest commercially available packaging or legible through it if the packaging is transparent.</td></tr>
</table>

Test Report

9.1.1	The name, trademark or other means of identification of the manufacturer or supplier.	Not provided by the applicant;	N/T
9.1.2	Type-identifying marking.	Not provided by the applicant;	N/T
9.1.3	Classification: FFP1, FFP2, FFP3. "NR" if the particle filtering half mask is limited to single shift use only. Example: FFP3 NR, or "R" if the particle filtering half mask is re-usable. Example: FFP2 R D	Not provided by the applicant;	N/T
9.1.4	The number and year of publication of this European Standard.	Not provided by the applicant;	N/T
9.1.5	At least the year of end of shelf life.	Not provided by the applicant;	N/T
9.1.6	The sentence ‘see information supplied by the manufacturer’, at least in the official language(s) of the country of destination, or by using the pictogram as shown in Figure 12b.	Not provided by the applicant;	N/T
9.1.7	The manufacturer’s recommended conditions of storage (at least the temperature and humidity) or equivalent pictogram, as shown in Figures 12c and 12d.	Not provided by the applicant;	N/T
9.1.8	The packaging of those particle filtering half masks passing the dolomite clogging test shall be additionally marked with the letter "D".	Not provided by the applicant;	N/A
9.2	Particle filtering half mask		
	Particle filtering half masks complying with this European Standard shall be clearly and durably marked with the following:		
9.2.1	The name, trademark or other means of identification of the manufacturer or supplier.	Not provided by the applicant;	N/T
9.2.2	Type-identifying marking.	Not provided by the applicant;	N/T
9.2.3	The number and year of publication of this European Standard.	Not provided by the applicant;	N/T
9.2.4	The symbols FFP1, FFP2 or FFP3 according to class.	Not provided by the applicant;	N/T
9.2.5	If appropriate the letter D (dolomite) in accordance with clogging performance. This letter shall follow the class designation (see 9.2.4).	Not provided by the applicant;	N/A
9.2.6	Sub-assemblies and components with considerable bearing on safety shall be marked so that they can be identified.	Not provided by the applicant;	N/A
10	Information to be supplied by the manufacturer		
10.1	Information supplied by the manufacturer shall accompany every smallest commercial available package	Not provided by the applicant;	N/T

Test Report

10.2	Information supplied by the manufacturer shall be at least in the official language(s) of the country of destination	Not provided by the applicant;	N/T
10.3	The information supplied by the manufacturer shall contain all information necessary for trained and qualified persons on	Not provided by the applicant;	N/T
	- application/limitations - the meaning of any colour coding - checks prior to use - donning, fitting - use - maintenance (e.g. cleaning, disinfecting), if applicable - storage - the meaning of any symbols/pictograms used	Not provided by the applicant;	N/T
10.4	The information shall be clear and comprehensible. If helpful, illustrations, part numbers, marking shall be added.	Not provided by the applicant;	N/T
10.5	Warning shall be given against problems likely to be encountered, for example: - fit of particle filtering half mask (check prior to use) - it is unlikely that the requirements for leakage will be achieved if facial hair passes under the face seal - air quality (contaminants, oxygen deficiency) - use of equipment in explosive atmosphere	Not provided by the applicant;	N/T
10.6	The information shall provide recommendations as to when the particle filtering half mask shall be discarded.	Not provided by the applicant;	N/T
10.7	For devices marked "NR", a warning shall be given that the particle filtering half mask shall not be used for more than one shift.	Not provided by the applicant;	N/T

Test Report

TEST DATA

Table 1 – 7.9.1 Total inward leakage

Model	LK-008					
Classification	FFP2					
Exercises	E1（%）	E2（%）	E3（%）	E4（%）	E5（%）	TIL（%）
A.R.	4.7	4.6	5.3	6.8	5.5	5.4
	4.6	4.5	6.5	8.1	5.3	5.8
	3.4	4.5	4.9	6.0	4.2	4.6
	5.2	5.1	6.2	8.0	4.9	5.9
	4.3	4.6	6.1	8.9	4.9	5.8
T.C.	5.6	5.8	6.5	7.7	6.5	6.4
	4.1	4.5	6.4	7.1	4.8	5.4
	5.1	5.5	5.9	7.0	5.0	5.7
	5.7	5.6	7.2	9.0	5.8	6.7
	4.3	5.6	7.1	8.9	5.9	6.4
Requirement	For particle filtering half masks fitted in accordance with the manufacturer's information, at least 46 out of the 50 individual exercise results (i.e. 10 subjects x 5 exercises) for total inward leakage shall be not greater than ~~25 % for FFP1~~ 11 % for FFP2 ~~5 % for FFP3~~			at least 8 out of the 10 individual wearer arithmetic means for the total inward leakage shall be not greater than ~~22 % for FFP1~~ 8 % for FFP2 ~~2 % for FFP3~~		
Result	P			P		

Testing Subject Family name of volunteer	Face Length (mm)	Face Width (mm)	Face Depth (mm)	Mouth Width (mm)
Luo	128	149	116	54
Chen	124	135	110	49
Liang	119	147	115	58
Chen	115	139	119	55
Yuan	107	125	110	52
Lai	118	135	117	55
Yang	115	127	124	53
Jiang	119	126	116	59
Feng	120	145	119	54
Zeng	109	123	115	52

Test Report

Table 2 – 7.9.2 Penetration of filter material

Model	LK-008					
Classification	FFP2					
Test flow rate (l/min)	95					
Test aerosol	Sodium chloride			Paraffin oil		
Sample performed	A.R.	S.W.	M.S.+T.C.	A.R.	S.W.	M.S.+T.C.
Measured Penetration (%)	2.2	1.8	1.6	4.6	4.3	4.2
	0.4	0.4	0.4	5.8	4.5	3.5
	0.2	0.3	0.4	4.3	4.7	5.8
Required (%)	FFP2: ≤ 6			FFP2: ≤ 6		
Result	P	P	P	P	P	P

Table 3 – 7.11 Flammability

Condition	Result	Assessment
As received	Burn for 0s	P
	Burn for 0s	
Temperature conditioned	Burn for 0s	
	Burn for 0s	
Required: when tested, the particle filtering half mask shall not burn or not to continue to burn for more than 5 s after removal from the flame.		

Test Report

Table 4 – 7.12 Carbon dioxide content of the inhalation air

Model	LK-008		
Samples	Sample 1	Sample 2	Sample 3
Measured CO_2 (%)	0.25	0.26	0.27
Average CO_2 (%)	0.26		
Required	The carbon dioxide content of the inhalation air (dead space) shall not exceed an average of 1,0 % (by volume)		
Result	P		

Table 5 – 7.16 Breathing resistance

	LK-008																
A.R	Flow rate		1					2					3				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.3	0.4	0.3	0.4	0.3	0.3	0.4	0.4	0.3	0.4	0.3	0.4	0.3	0.4	0.3
		95 l/min	1.3	1.4	1.3	1.4	1.3	1.3	1.4	1.4	1.4	1.4	1.3	1.5	1.3	1.3	1.3
	Exhalation	160 l/min	1.6	1.8	1.7	1.8	1.8	1.7	1.8	1.7	1.8	1.7	1.8	1.9	1.7	1.7	1.9
S.W.	Flow rate		4					5					6				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.3	0.4	0.3	0.4	0.4	0.3	0.3	0.3	0.3	0.3	0.3	0.4	0.3	0.3	0.4
		95 l/min	1.4	1.3	1.3	1.4	1.3	1.4	1.4	1.3	1.3	1.4	1.3	1.4	1.3	1.5	1.3
	Exhalation	160 l/min	1.7	1.8	1.7	1.7	1.7	1.8	1.8	1.8	1.8	1.8	1.8	1.9	1.7	1.7	1.9
T.C.	Flow rate		7					8					9				
			A	B	C	D	E	A	B	C	D	E	A	B	C	D	E
	Inhalation	30 l/min	0.3	0.4	0.3	0.4	0.4	0.3	0.4	0.4	0.4	0.3	0.3	0.4	0.3	0.3	0.3
		95 l/min	1.3	1.3	1.3	1.4	1.3	1.4	1.5	1.4	1.3	1.4	1.3	1.4	1.3	1.5	1.4
	Exhalation	160 l/min	1.7	1.8	1.7	1.8	1.8	1.7	1.8	1.8	1.8	1.7	1.8	1.9	1.7	1.7	1.9
Result	P																

A: facing directly ahead;
B: facing vertically upwards;
C: facing vertically downwards;
D: lying on the left side;
E: lying on the right side;

Test Report

Equipement

List of test equipment used:

Serial No	Description	Model/Trade Mark	Next Calibration Date
ZSTE-001	Ambient Barometer	DYM3	24th Jun. 2021
ZSTE-002	Ambient temperature and Humidity recorder	Cos-03	9th Apr. 2021
ZSTE-009	Digital Pressure Gauge	BG80-B-21F-0N21	2nd Apr. 2021
ZSTE-017	Two Row Stopwatch	PC2810	6th Apr. 2021
ZSTE-030	Digital Data Collector	34970A	2nd Apr. 2021
ZSTE-030.01	20-Channel Armature Multiplexer	34901A	2nd Apr. 2021
ZSTE-070	Pull-Push Force tester	NK-300	3rd Apr. 2021
ZSTE-082	Digital Vernier Caliper	0-200_0.01mm	11th Apr. 2020
ZSTE-083	Wind Speed Meter	Testo416	19th Jun. 2020
ZSTE-108	Electronic Scale	JJ224BC	29th May. 2020
ZSTE-115	Graduated Cylinder	100ml	28th May. 2024
ZSTE-122	Beaker	500ml	28th May. 2024
ZSTE-140	Weight	1kg	19th Jun. 2022
ZSTE-200	Aerosol generator	TDA-5B	14th May. 2021
ZSTE-215	Air quality analyzer	M2000	24th June. 2021
ZSTE-216	Air quality analyzer	M2000	24th June. 2021
TSGK-T-005	Penetration of Filter Material Tester	LSK	9th Mar. 2021
TSGK-T-056	Breath Resistance Tester	RL 2051C	5th May. 2021
TSGK-T-002	Flammability	KP415	9th Mar. 2021
TSGK-T-045	Leakage with Enclosure	RL 2001	5th May. 2021

END TEST REPORT