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Technical Construction File

File No. : LZ2017062901ST

According to

EN ISO 8317:2015

related to the

PLASTIC BOTTLE FOR E-LIQUID

**Models: XM-001A, XM-002A, XM-003A, XM-004A, XM-005A, XM-006A,
XM-007A, XM-008A, XM-009A**

presented by

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1. Declaration of conformity

EC Declaration of conformity

YUHUAN XINMENG PLASTIC PRODUCT CO.,LTD

Medical Packing Industrial Zone, Lupu Town, Yuhuan City, Zhejiang Province, 317608
China.

Certify that the product described is in conformity with the standard
EN ISO 8817:2015 as amended

Product Name : PLASTIC BOTTLE FOR E-LIQUID

**Models: XM-001A, XM-002A, XM-003A, XM-004A, XM-005A, XM-006A, XM-007A,
XM-008A, XM-009A**

2017年7月9日

Issue place and date



Signature of authorized personnel

2. General description

The product is a kind of plastic bottle for e-liquid.

Material of Childproof cap	PP
Material of Childproof and tamper evident cap	outside cap: PP, inner cap: LDPE
Material of dropper	LDPE
Material of bottle	PET or LDPE plastic
Volume	3ml/5ml/10ml/15ml/20ml/30ml/50ml/60ml/100ml/120ml
Cap type	child proof cap, childproof and tamper evident cap
Application	E- liquid filling for health care

Basically, this kind of product belongs to general product and with low risk when using it. All possible risk have been analysis after assessment of conformity report and been prevent by suitable ways. The main risk of this kind of product could be ignoring the type characteristics to the product.

In addition to the safety of the product mentioned above, the compliance of EN ISO 8317:2015 is main important part of putting CE mark on the product. As for the compliance of EN ISO 8317:2015 the inspection and quality control carried out. All inspection information is included in this technical construction file.

In order to ensure the conformity for CE marking for these products, some main European and/or International directive and standards have been used to made assessment of conformity. EN ISO 8317:2015 Child-resistant packaging —Requirements and testing procedures for reclosable packages

3. Variations of the series products

Regarding the whole family of the series, they can be divided into various different groups according to their color, they are: XM-001A, XM-002A, XM-003A, XM-004A, XM-005A, XM-006A, XM-007A, XM-008A, XM-009A

All models are with the same structure but with some small differences as described as the dimension and weight are different.

To present the conformity of this series product with EN ISO 8317:2015, we discuss the conformity systematically with the relative standards for XM-001A as a basic evaluation in clause.

4. Quality control system

In order to ensure the conformity of the series production, the **YUHUAN XINMENG PLASTIC PRODUCT CO.,LTD** has taken the related procedures mentioned below :

(1) Apply for the consultant form the qualified body in Turkey.

The XINMENG has applied for the consultant from Technical Inspection Certification.

The complete technical construction file (TCF) have been established before applying for the CE marking certificate.

(2) Carry out the inspection for parts and components according to the TCF

Before the assemblies of the series production, the QC engineers of XINMENG has to check and inspect the technical specifications and intended functions of parts and components to ensure the correct use of them according to the contents of TCF and principle described in the related technical information.

(3) Carry out the inspection & testing for the products before packing

Before packing the products, the QC engineers of XINMENG have to do the necessary inspection and testing to ensure the conformity of related requirements. In particular, they should do the testing and inspection of outer feature.

(4) Carry out the inspection for the package.

After finishing the necessary inspection and testing for the products, an inspection for the packing has to be done to ensure the necessary elements being included in this packing before shipment.

(5) Provision for the change of design

Any change of the products described in this TCF must be checked in detail and written down again in the TCF by the designer of XINMENG if the change may effects the related mechanical characteristics.

(6) Provision for the Quality Assurance

For the provisions of internal control measures to ensure the conformity of series production of the machines, XINMENG has built an internal quality control system in accordance with the international standard of ISO-9001.

5. Assessment of conformity and Test Report

Clause	Requirement-Test	Verdict and Result-Remark
EN ISO 8317:2015 Child-resistant packaging —Requirements and testing procedures for reclosable packages		Pass
1	Scope	-
	This International Standard specifies performance requirements and test methods for reclosable packages designated as resistant to opening by children. Acceptance criteria are given for the packages when tested by specified methods. These methods not only provide a measure of the effectiveness of the packaging in restricting access by children, but also cover the accessibility to the contents by adults. This International Standard is applicable to reclosable packages for any product intended to be exposed or removed from the packaging in normal use. This International Standard is intended for type approval only and is not intended for quality assurance purposes.	Pass. This product is within this scope.
2	Terms and Definitions	-
3	Requirements	-
3.1.1	General	-
	Only new packages shall be submitted for testing. The container and closure system tested shall be representative of those in normal use and shall include any wad or liner, if this is an integral part of the closure system. Packages may be tested individually or as part of a series of similar packaging submitted at the same time. When testing a series of similar packaging, the requirements in 3.1.2 shall be applied. In specifying a series of similar packaging, the following essential characteristics shall be taken into consideration.	Pass. This requirement is complied with.
3.1.2	Evaluation of a series of similar packaging	-
3.1.2.1	Rationale	-
	The rationale for a series of similar packaging, which discloses the degree of commonality, shall be recorded.	Pass. This requirement is complied with.
3.1.2.2	Closures	-
	If a series of closures differ only in diameter, but are similar in all essential characteristics, where the largest diameter is smaller than or equal to 1,5 times the smallest diameter, then the largest and smallest size shall be tested. If a series of closures differ only in diameter, but are similar in all essential characteristics, where the largest diameter is greater than 1,5 times the smallest diameter, then the largest, smallest and one intermediate size shall be tested.	Pass. This requirement is complied with.
3.1.2.3	Containers	-

Clause	Requirement-Test	Verdict and Result-Remark
	If the containers of the packaging differ only in capacity and the closures differ only in diameter but are similar in all essential characteristics, the largest and smallest diameters of closure fitted to the largest and smallest container shall be tested, this means normally four container/closure combinations subject to the 1,5 times diameter rule given in 3.1.2.2. If several container shapes are involved, but all other characteristics are the same and the closures are identical or differ only in diameter, a selection from the range shall be made to test each body shape and to ensure that at least four container/closure combinations are tested. If all the packages specified in 3.1.2.2, 3.1.2.3 and 3.1.2.4 pass the test, containers and closures of intermediate sizes in the same series shall be regarded as conforming to this International Standard.	Pass. This requirement is complied with.
3.1.2.5	Additions and modifications	-
	If, after a range of packaging has been tested and approved, sizes of containers and closures outside the dimensions of the accepted range are to be added, the packages shall be tested as specified in 3.1.2.2, 3.1.2.3 and 3.1.2.4 to extend the range specified. Minor modifications of container or closure can be evaluated by the development and provision of mechanical test data showing compliance.	Pass. This requirement is complied with.
3.2	Test panels	-
	Testing shall be performed with two panels of people a) a test with young children aged between 42 and 51 months old, inclusive, b) a test with adults aged between 50 and 70 years old, inclusive.	Pass. a)
3.3	Performance requirements	-
3.3.1	Requirements concerning children	-
3.3.1.1	Using a test panel of 200 children	-
	When the package is tested in accordance with 4.4.4, the following requirements shall be met: a) at least 85 % of the 200 children in the test panel shall be unable to open the package within the first 5 min without a demonstration; b) at least 80 % of the 200 children in the test panel shall be unable to open the package within another 5 min after a demonstration has been given to those children unable to open the package in the first 5 min.	Pass. a)
3.3.1.2	Using the sequential test procedure	-
	If less than the full test panel is used in accordance with 5.1.2, the result shall be obtained from completing Figure 1 and Figure 2.	Pass. This requirement is complied with.
3.3.2	Requirements concerning adults	-
	When the package is tested in accordance with 4.5.3, 90 % of the eligible adults shall be able to open and properly reclose	Pass. This requirement is

Clause	Requirement-Test	Verdict and Result-Remark
	the packaging.	complied with.
4	Test procedures	-
4.1	Test supervision	Pass. This requirement is complied with.
	All procedures shall be performed under the supervision of (an) impartial and appropriately qualified person(s). For the child test, the supervisor(s) shall also be skilled in dealing with children.	-
4.2	Sample packages	-
	Sufficient packages shall be supplied conforming to the container and closure drawings and specifications to enable a representative sample to be selected for testing by the supervisor and to provide a reserve for reference purposes. In every test, a new package shall be provided for each member of the test group.	Pass. This requirement is complied with.
4.3	Preliminary checking and preparation	-
	Before packages are tested, each package shall be opened and properly reclosed. Packages which incorporate a tamper-evident feature shall have the tamper-evident feature disabled. No hazardous product shall be used to fill any packaging submitted for test. A suitable substitute product shall be used for both the adult and child tests. When a substitute product is used, packages up to a volume of 1 l shall be filled to their nominal size capacity (i.e. as sold); packages greater than 1 l volume shall be filled with 1 kg of solid or 1 l of liquid substitute product as appropriate. If the closure system used on the package to be tested is torque dependant, then the packages shall be assembled by the test supervisor by hand. The packages shall then be closed using a torque meter up to a specified torque, and left for 72 h at room temperature prior to conducting tests. This is to allow materials (e.g. closure/liner/wad) to take “a set”. Application torque should be recorded in the test report. Once the packages have been prepared for testing they should be handled carefully.	Pass. This requirement is complied with.
4.4	Child test	-
4.4.1	Guidance for persons supervising tests	-
4.4.1.1	Surroundings and personnel	-
	The surroundings and personnel should be familiar and friendly.	Pass. This requirement is complied with.
4.4.1.2	Presence of parents	-
	Children perform differently when the package is presented to them in the presence of their parents. Involvement of parents introduces a bias, as children tend to perform in accordance with implicit or explicit parental expectations. It is important, therefore, to avoid parental	Pass. This requirement is complied with.

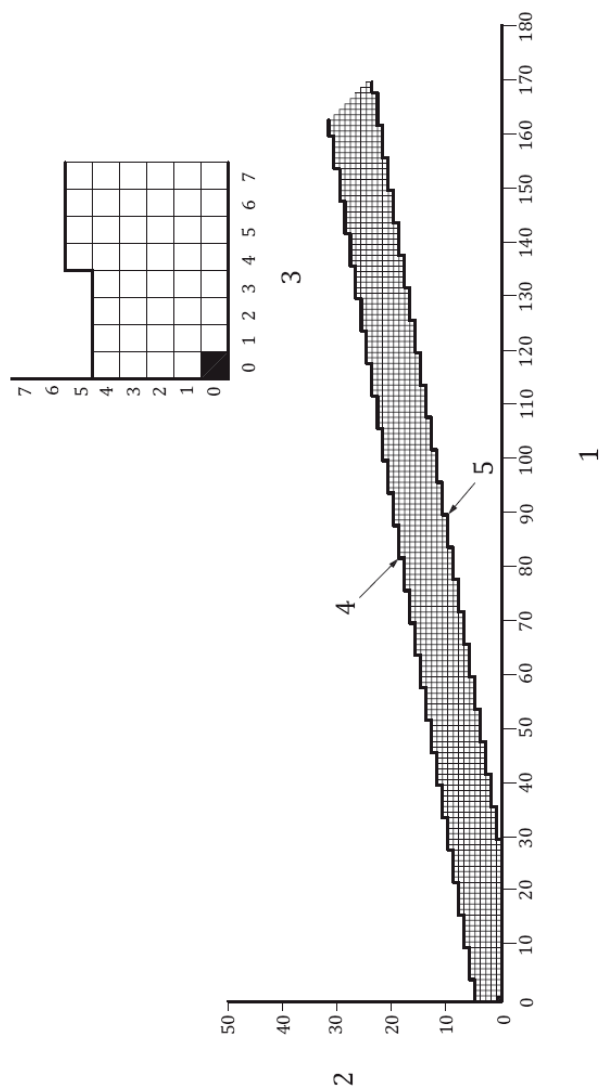
Clause	Requirement-Test	Verdict and Result-Remark
	influence by excluding them from the test area.	
4.4.1.3	Presence of official observer	-
	If required by the regulatory body, an official observer may be present but the requirements of 4.4.1.1 still apply.	Pass. This requirement is complied with.
4.4.1.4	Social circumstances of the children	-
	There is a highly significant correlation between the success rate in opening packages and the social class of children. Children should be selected to represent as closely as possible the different social, ethnic and cultural origins of the population of the country, not just of the immediate district in which the test is conducted. If this is not possible, any clear-cut deviation from this method of selection should be documented.	Pass. This requirement is complied with.
4.4.1.5	Avoidance of extraneous distractions	-
	During the test, children should be removed from the general student body in the test location and protected from extraneous distractions.	Pass. This requirement is complied with.
4.4.1.6	Seating the children	-
	The children should be seated in pairs at tables or desks arranged in a familiar manner, or they may sit on the floor if they wish.	Pass. This requirement is complied with.
4.4.2	Composition of test group	-
	Enough children to ensure 200 valid participants between the ages of 42 and 51 months inclusive, with an even distribution of age and sex, shall be available. They shall all be healthy with no evident physical handicap which might affect manual dexterity. They shall not have taken part in more than one previous test and, in that test, a package of a different type with opening arrangements based on a different principle shall have been involved. If a child is used on more than one test panel, it is desirable that there should be at least one week between the tests. It is preferable for only one test to be performed in one testing session, because there might be a statistically significant difference in the results between the first and second package tried.	Pass. This requirement is complied with.
4.4.3	Test location	-
	The children shall perform the test in any place with which they are familiar or relaxed, for example, in their usual school or nursery, but they should be removed from the general school population and separated from extraneous distractions. A minimum of three sites shall be used, selected from different demographic areas.	Pass. This requirement is complied with.
4.4.4	Procedure	-
	The test may be performed on all 200 children or by a sequential procedure. If the latter is used, the number of children tested will depend on the results obtained (see 5.1.2).	Pass. This requirement is complied with.

Clause	Requirement-Test	Verdict and Result-Remark
	<p>When testing sequentially, the age and sex constraints specified in 4.4.2 shall be adhered to. The children shall be tested in pairs, each pair being monitored by one supervisor. If desired, a number of pairs (up to five) may be tested in the same room at the same time, provided that arrangements are such that they cannot distract other pairs. They may adopt any attitude or position they find convenient. Should a child wander off during the test, action by the supervisor(s) shall be limited to leading the child back to its place and requesting that he or she continue the test, without any additional instruction being given concerning the opening of the package; this fact shall be included in the report.</p> <p>Each child shall be given a package with the request that it be opened by whatever means the child wishes to use; in order to achieve this, 5 min shall be allowed. No attempt shall be made to stop a child using its teeth or any other method of opening the package. However, no tools or implements should be accessible which might be used by the child, except where such tools or devices are specifically supplied as part of the design of the child-resistant package; where this is so, the children shall have unobtrusive access to that tool, but it shall not be drawn to their attention until and unless it is used in the demonstration. If a child succeeds in opening the package within 5 min, that child shall remain in the test area until the end of the period. Any child failing to open the package in 5 min shall then watch a package being opened and reclosed by the supervisor in full view, without emphasis being placed on the actions of opening and without any verbal instruction. The child shall then have a further 5 min to open the package.</p>	
4.4.5	Expression of results (see also 5.1)	-
	<p>After each period of 5 min, it shall be recorded whether a child fails to open the package; if the child succeeds, it shall be recorded whether this was before or after a demonstration. It shall also be recorded whether teeth (or any other means) were used to open the package.</p>	<p>Pass. This requirement is complied with.</p>
4.5	Adult test (50 years to 70 years old inclusive)	-
4.5.1	General	-
	<p>Unlike child testing, there is no need for the adults to be tested at any particular place or time.</p>	<p>Pass. This requirement is complied with.</p>
4.5.2	Composition of test group	Pass
	<p>Enough adults shall be in the test group to ensure that 100 valid participants shall be available to conduct the test after screening, which is done by obtaining a negative answer to the following question: “Are you professionally concerned with the design, manufacture or use of child-resistant packaging?” In order to</p>	-

Clause	Requirement-Test	Verdict and Result-Remark
	<p>elicit this information and, at the same time, to ascertain that the individual is literate, it is permitted to present the question on a typed (printed) form and give it to the person to read. Persons with obvious physical handicaps which may affect manual dexterity should not be approached and those unable to understand the instructions should be discounted. The purpose of the test shall be explained in reasonable detail, but no demonstration shall be given. The 100 valid participants shall be randomly selected between the ages of 50 and 70 in accordance with the criteria specified in Table 1.</p>	
4.5.3	Procedure	-
	<p>The adult test panel shall consist of 100 panellists. Those panellists failing the screening test shall be discounted and their place taken by new panellists. Each adult shall be given a package, together with any accessories and written instructions on how to open and reclose it properly that will be printed in or on the package when supplied to a consumer. No demonstration of how to open or reclose the package shall be given. Acting independently, a period of 5 min shall be allowed for the test participants to familiarize themselves with the package to be tested by reading the opening and closing instructions and attempting to open and reclose it properly. Those panellists who successfully open the test package within the 5 min period shall be given a new identical package with a request to open and reclose this one as quickly as possible. A 1 min test period shall be allowed for the panellists to open and properly reclose the package. If, in the period of 5 min, a panellist is unable to open the package being tested he or she will be given a screening test. This screening test shall consist of asking the panellist to open and reclose two conventional non-child-resistant closures in 1 min each, these being</p> <p>a) a 28 mm diameter continuous screw thread closure applied at 1,1 Nm torque onto a 25 ml to 50 ml cylindrical plastic container</p> <p>b) a 28 mm diameter “snap-on” closure applied to a 25 ml to 50 ml round plastic container.</p> <p>Panellists unable to open or reclose both of these packages in the 1 min screening test are to be discounted from the adult panel results. Panellists who are able to open both these packages are counted as a failure in the overall result.</p>	<p>Pass. This requirement is complied with.</p>
4.5.4	Expression of results (see also 5.2)	-
	Record whether or not the adult succeeds in opening and properly reclosing the package in the 1 min test periods, including the screening test if carried out, see 4.5.3 and 3.3.2.	Pass. see 4.5.3 and 3.3.2
5	Assessment of results	-
5.1	Child test	-
5.1.1	Success/failure	-

Clause	Requirement-Test	Verdict and Result-Remark
	The result of the test is a failure if the child succeeds in opening the package (or gaining access to the contents).	Pass. This requirement is complied with.
5.1.2	Sequential method	-
5.1.2.1	Recording test results on a graph	-
	A separate chart shall be prepared for results obtained before and after a demonstration. As each result is obtained, it shall be plotted on the appropriate chart by filling in a square as follows: — fill in a square immediately to the right of the previous result on Figure 1 if the test child failed to open the package (or gain access to the contents) in the first 5 min, and on Figure 2 if the test child failed to open the package (or gain access to the contents) in the second 5 min, i.e. the result is a success (see 5.1.1); — fill in a square immediately above the previous result on Figures 1 and 2 if the test child succeeded in opening the package (or gaining access to the contents) in the first 5 min, or only on Figure 2 if the test child succeeded in opening the package (or gaining access to the contents) in the second 5 min, i.e. the result is a failure (see 5.1.1).	Pass. This requirement is complied with.
5.1.2.2	Determination of the results	-
	The package shall be deemed to have — passed the test as soon as the trail of filled squares passes below limit line 1 on both Figure 1 and Figure 2, — failed the test as soon as the trail of filled squares passes above limit line 2 on either Figure 1 or Figure 2. If neither occurs, the results shall be assessed in accordance with the requirements specified in 3.3.1.	Pass. This requirement is complied with.
5.1.3	Full test	-
	If a sequential procedure is not used and the full number of children is tested, the results shall be assessed in accordance with the requirements laid down in 3.3.1.	Pass. This requirement is complied with.
5.2	Adult test	-
	The result of the test is a success if 90 % or more of the eligible adults are able to open the package in the first 5 min test period and open and properly reclose it in the 1 min test period. An eligible adult is one who has not been discounted by the screening test given in 4.5.3. The result of an individual adult test is a failure if the eligible candidate opened the package in the first 5 min test but failed to open and properly reclose the package in the 1 min test period.	Pass. These requirements are complied with.
5.3	Overall test result	-
	Only packages which satisfy both the child and the adult test	Pass.

Clause	Requirement-Test	Verdict and Result-Remark
	criteria as specified in 3.3.1 and 3.3.2 shall be deemed to conform to this International Standard.	These requirements are complied with.
6	Test report	-
6.1	General	-
	At least the following information shall be recorded by the supervisor: a) the name of the agency carrying out the test; b) the date(s) on which the test was carried out; c) the name and address of the manufacturer and/or filler/packer of the package tested; d) the name(s) of the person(s) supervising the test; e) the specification number, drawing numbers and a complete description of the package tested; f) a direct quotation of the exact instructions, etc. given to the adults and the children during the test; g) a copy of the manufacturer's instructions on opening and reclosing the package given to the adults during the test; h) a description of the substitute product used in the test.	Pass. These requirements are complied with.
6.2	Child test	-
	At least the following information shall be recorded: a) the location of the test; b) the number, age and sex of the children involved; c) the number of children, together with their age and sex, who successfully opened the package 1) before a demonstration, 2) after a demonstration, 3) the means used by the children who were successful in opening the package; d) if the full child test has been carried out, the percentage number of children who failed to open the package.	Pass. These requirements are complied with.
6.3	Adult test	-
	At least the following information shall be recorded: a) the number, age and sex of the adults involved; b) the number, age and sex of adults who successfully opened and reclosed the package properly; c) the number who opened but could not reclose the package properly; d) the number who failed to open the package.	Pass. These requirements are complied with.
6.4	Additional (optional) information to be recorded	-
	Any other information deemed to be useful in assessing the interpretation of the result shall be recorded.	Pass. These requirements are complied with.
6.5	Overall test result	-
	It shall be recorded whether the overall result of the test was a pass or a failure.	Pass. These requirements are complied with.

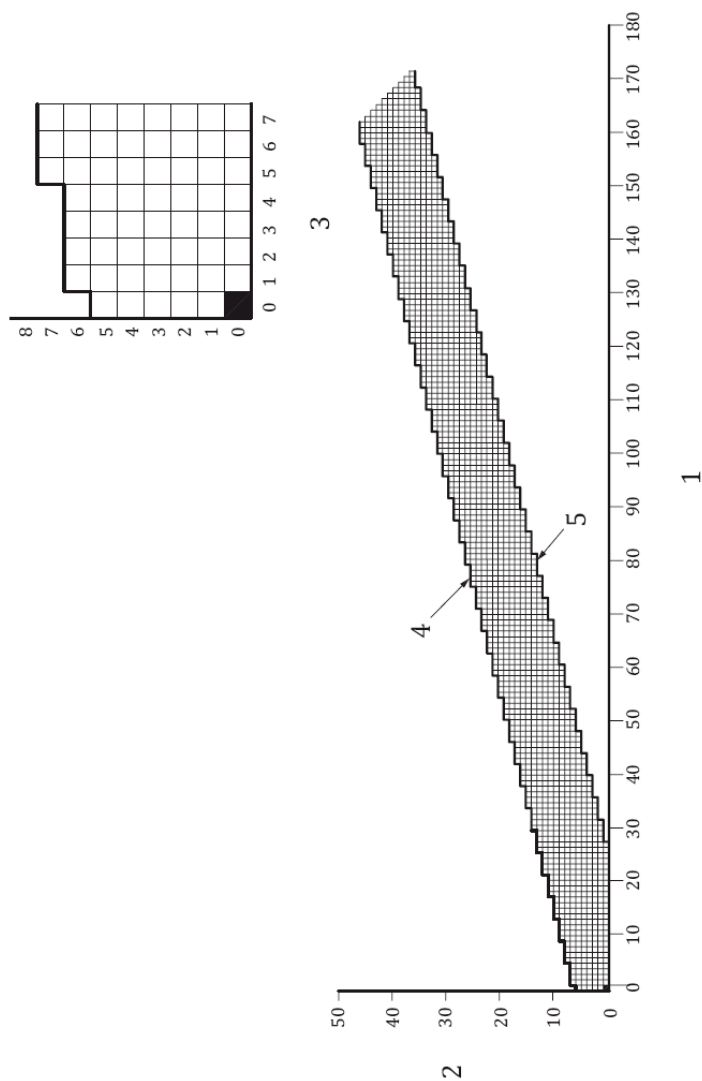


Key

- | | | | |
|---|-------------------------------|---|--------------|
| 1 | number of packages not opened | 4 | limit line 2 |
| 2 | number of packages opened | 5 | limit line 1 |
| 3 | enlargement of chart scale | | |

NOTE Acceptable quality limit (AQL) = 10 %; limiting quality (LQ): 20 %; $\alpha = \beta = 5 \%$, where α is the producer's risk; β is the consumer's risk.

**Figure 1 — Chart of a sequential child test procedure (before demonstration)
for child-resistant reclosable packages**



- Key**
- | | | | |
|---|-------------------------------|---|--------------|
| 1 | number of packages not opened | 4 | limit line 2 |
| 2 | number of packages opened | 5 | limit line 1 |
| 3 | enlargement of chart scale | | |

NOTE Acceptable quality limit (AQL) = 15 %; limiting quality (LQ): 25 %; $\alpha = \beta = 5 \%$, where α is the producer's risk; β is the consumer's risk.

Figure 2 — Chart of a sequential child test procedure (after demonstration) for child-resistant reclosable packages

Table 1 — Composition of the adult test group

Age range (years)	Male	Female	Total
50 to 54	8 or 7	17 or 18	25
55 to 59	7 or 8	18 or 17	25
60 to 70	15	35	50
Total	30	70	100

6. Product Photos



P1



P2



P3