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QUALITY MANUAL		
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1. GENERAL PART

1.1. Purpose of this document

The purpose of this document is to collect and systematize all technical parameters and requirements for polyethylene tubes and to clearly specify the terms of delivery, which are subject to the manufacturer's and customer's acceptance.

1.2. Subject and scope


The subject of this CTA are polyethylene tubes manufactured by DAFO PLASTICS, intended for the packaging of cosmetic products.

The document describes:

- a.** technical standards for polyethylene tubes,
- b.** print parameters
- c.** methods of quality control,
- d.** principles of handling complaints.

1.3. Changes

Any changes regarding the issues described herein may only be made in writing. The document change sheet can be found in section 9 CTA.

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1.4. Terminology and definitions

Monolayer polyethylene tube - mono-layer plastic packaging, made by thermoforming from a material that is a mixture of LDPE (low-density polyethylene) and HDPE (high-density polyethylene), ending with a head closed by a screw-on or a snap-on cap on one side, and open on the other.

Multilayer polyethylene tube - multilayer plastic packaging, made by coextrusion of a material that is a mixture of LDPE (low-density polyethylene) and HDPE (high-density polyethylene) with the possibility of using an EVOH barrier, where the adhesive is glue, ending with a head closed by a screw-on or a snap-on cap on one side, and open on the other.

Tube body - a cylinder of fixed diameter and length, extruded from polyethylene with a fixed mixture.


Head - conical, threaded element joint with the body, made of plastic consisting of HDPE or a mixture, with or without dye. The types of threads, diameters of dispensing holes and types of necks, diameters and types of caps are described in Table No. 1.

Neck - threaded part of the head

Membrane - element made of aluminum or polypropylene film, thermally attached to the dispensing hole of the head, used for additional sealing.


Marker (lay mark) – marker printed on the tube's body, in line with the design.

Screw-on or snap-on cap - polypropylene element closing the tube from the head side, made by injection, screwed in or attached to the threaded part of the head; the sizes and types of caps are described in Table 2 in Section 2.

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Sample- 2 sets of tube bodies - one for the Customer, the other for DAFO PLASTCS, each consisting of three tubes signed by the Customer and by DAFO.

**Post-production samples are being stored for 36 months, and are disposed of after this period.*

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The sample reflects the final qualitative and technical arrangements between the Parties.

2. SCOPE OF TECHNICAL REQUIREMENTS


2.1. Raw materials for tube manufacture should have appropriate **Safety Data Sheets** issued by their manufacturers. Materials for manufacture should have **Quality Certificates** issued by their manufacturers.

2.2. Tube body:

- color - transparent, white, black or other, as determined in accordance with the PANTONE number or a sent sample - tolerance range ± 1 hue in relation to the accepted sample,
- length - in accordance with the accepted order and design - tolerance range ± 1.5 mm,
- ovality- controlled on the Panasonic HGC 1200 device
- wall thickness depending on the diameter is described in table 1:

Table No.1 applies to extrusion and co-extrusion		
tube diameter (mm)	wall thickness (mm)	tolerance +/- (mm)
16	0.42	0.04
19	0.42	0.04
25	0.5	0.04
30	0.5	0.04
35	0.5	0.04
40	0.5	0.04
50	0.52	0.04

Table No.2 applies to injection blow molding		
16	0.5	0.1
19	0.5	0.1
25	0.5	0.1
30	0.5	0.1
35	0.5	0.1
40	0.5	0.1

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2.3. The head of the tube should be permanently and firmly welded to the body. The whole weld should be tight. The threaded part of the head (neck) should be in accordance with the markings contained in Table 2 in section 2.5.

2.4. The membrane should be permanently fixed to the head's dispensing hole. Fastening stability should be checked by a tear test.


2.5. The shape, diameter and type of a screw-on or a snap-on cap should be in accordance with the specification agreed with the Customer, in the approved Order Confirmation. The color of a screw-on or a snap-on cap is determined in accordance with the PANTONE number or a sent sample (cap or polypropylene template); color tolerance range ± 1 hue.

* in case of using dyes, there may be differences in the opening and closing of the closures.

Thread types are described in the table:

Table No.2

tube diameter Φ [mm]	type of thread	type of neck	type of cap / diameter of the dispensing hole	
16	M9x1,25	standard (ST)	ST	1;2;3;4
16	M9x1,25	cannula	SL	1;1,5;2
19	M11x1,5	standard (ST)	ST	1.5;2;3;4
19	M9x1,25	standard (ST)	ST	1;1,5;2;3;4
19	M9x1,25	cannula	SL	0;1,5
19	M14x1,25	lip-gloss	SL	2,2 \pm 0.2
25	M11x1,5	standard (ST)	ST,FT	1.5;2;3;4
25	M9x1,25	cannula	SL	1,45 \pm 0.05
30	M15x1,5	standard (ST)	ST; SL	1,5;2;3;4;5;6;8- with aluminum seal only
30	M9x1,25	cannula	SL	1.5

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30	Snap-on	Snap-on	FT	10±0.1
35	M15x1,5	standard (ST)	ST;SL;FT	1,5;2;3;4;5;6;8- only with aluminum seals
35	M9x1,25	cannula	SL	1.5
35	Snap-on	Snap-on	FT	10±0.1
40	M15	standard (ST)	ST; SL; FT	1,5;2;3;4;5;6;8- with aluminum seal only
40	Snap-on	Snap-on	FT	10±0.1
50	TR22x3	standard (ST)	ST; FT	3;4;5;8;12
50	Snap-on	Snap-on	FT	10±0.1

ST – standard

SL – softline


FT – flip-top

2.6. Print on the tube:

- made with the dry offset method up to 8 colors:
 - color tolerance range ± 1 hue in relation to the template,
 - print alignment tolerance range ± 0.3 mm
 - background joining tolerance up to 2 mm
 - tolerance range for positioning the print along the tube's longitudinal axis relative to an assembled screw-on or snap-on cap (Y axis) $\pm 5\%$,
 - print height tolerance ± 1.5 mm;

- made with the silkscreen method up to 3 colors:
 - color tolerance range ± 1 hue in relation to the sample,
 - print alignment tolerance range ± 0.5 mm (first run), ± 1 mm (second run),
 - tolerance range for positioning the print along the tube's longitudinal axis relative to an assembled screw-on or snap-on cap (Y axis) $\pm 5\%$,
 - print height tolerance ± 1.5 mm;

- made using the hybrid method (flexo/silkscreen/in-line foiling):
 - print alignment tolerance range:

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- +/- 0.05-0.2 mm (flexo), +/- 0.1-0.4 mm (silkscreen) (greater tolerances are created on colored tubes where the material is less thermally stable)
- +/- 0.2-0.5 mm in the case of combining in-line foil and other printing techniques
- another transition on the machine, overlay tolerance +/- 0.5 mm compared to the first transition
- tolerance for line thickness: +/- 0.05 mm (flexo), +/- 0.05 mm (silkscreen) , +/- 0.1 mm (inline foil)
- tolerance range for positioning along the tube's longitudinal axis relative to an assembled screw-on or snap-on cap (Y axis) $\pm 5\%$,
- print height tolerance $\pm 1.5\text{mm}$;

- digital print (4 CMYK colors):
 - color tolerance range ± 1 hue in relation to the sample
 - print alignment tolerance range ± 0.2 mm,
 - background joining tolerance up to 2 mm,
 - tolerance range for positioning along the tube's longitudinal axis relative to an assembled screw-on or snap-on cap (Y axis) $\pm 5\%$
 - print height tolerance +/- 1.5mm
- decorating with foil in any color by means of hot-stamping (HS):
 - print alignment tolerance range ± 0.5 mm (first run), ± 1 mm (second run)
 - tolerance range for positioning along the tube's longitudinal axis relative to an assembled screw-on or snap-on cap (Y axis) $\pm 5\%$,
 - print height tolerance $\pm 1.5\text{mm}$;

* In case of using combined printing techniques, tolerance ranges for the positioning of the print may change. With combined techniques, tolerances are added up.

* Blurs or underprints with an area of less than 1mm² are allowed, up to 2 in the field of view; however, these must not make the text illegible.

* The correctness of barcodes is controlled on the MICROSAN LVS-9510 BARCODE VERIFIER DEVICE

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2.7. Varnish:

- Matt,
- Glossy,
- the distance of the varnish from the edge of the tube not less than 1 mm.

2.8. Packaging and labelling method:


Tubes are packed vertically with the open end up in cardboard boxes with bottom measurements of 400 mm x 600 mm and height depending on the tubes' length. The boxes are lined with polyethylene bags, whose loose ends overlapped, and then the box is closed with a lid. The number of tubes in boxes is shown in Table No. 3:

Table No.3:

Tube diameter (mm)	Quantity per carton (pcs)
16	945
19	667
25	374
30	259
35	186
40	140
50	88

Each box has an information label with the manufacturer name, customer name, product number and name, customer's product number, internal production number, customer order number, quantity of items in the box, and QC identification.

The boxes are stacked on pallets with measurements of 1200 x 800 mm, up to a maximum height of 2000 mm. Protective foil is put on the bottom of the pallet and on the last layer of boxes, and the whole is wrapped with stretch foil.

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3. TRANSPORT AND STORAGE

Transport conditions: the tubes should be transported in covered means of transport in a way that protects them against direct weather and against dirt or damage (mechanical and chemical). The tubes should not be transported together with odor-emitting materials.


3.1. Storage conditions: the tubes should be stored in the manufacturer's packaging, packed in the same way as at the time of collection. The boxes should be stored in closed rooms, with neutral pH, dry, properly ventilated and away from odors.

3.2. Storage

Empty tubes should be stored no longer than 6 months from the date of purchase, in closed rooms away from heating devices (1m).

Tubes should be protected from direct sunlight.

1. at ambient temperatures below 50°C
2. above the temperature of 10°C
3. maximum relative air humidity 70%
4. the packages should undergo 48h quarantine at room temperature before being ready for packaging.

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4. METHODS OF QUALITY CONTROL

4.1. Definitions

Acceptable Quality Limit (AQL) – a level of quality corresponding to the lowest tolerable average level of process quality; refers to a sequence of batches subject to successive acceptance checks

Non-compliant unit - a unit of product with one or more non-compliances

Batch - a set of product units the sample should be taken from and checked in order to determine compliance with the acceptance conditions. DAFO PLASTICS usually considers a batch of goods to be a quantity of homogeneous product covered by one order number


Test plan - a strictly defined procedure, indicating the number of units tested from each product batch (**sample quantity**), together with the criteria for determining compliance of a batch (**qualifying number, disqualifying number**)

Sample - one or more product unit, taken from the batch for inspection. Samples are taken randomly, using the "blind method".

Defect or non-compliance - deviation from the quality property that makes the product not meet certain requirements. Non-compliances in DAFO have been broken down due to their importance into critical and acceptable.

Critical defect (non-compliance) - unacceptable defect, disqualifying the use of the finished product as intended.

Acceptable defect (non-compliance) - a defect that is found passable.

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4.2. Description of non-compliance

4.2.1. Critical defects (non-compliances):

technical:

- no cap
- crooked cao
- loose cap
- tube leakage (checking the tightness of the package consists in immersing the tube with or without the cap (in the case of the "0" cannula) in a container with water and injecting air into it); the tubes also undergo the 24h test

tube body:


- perforation
- measurements outside tolerance
- contamination or scratches visible to the naked eye from a distance of about 30 cm, in dispersed daylight;
- colors not matching the template up to ± 2 hues

tube head:

- perforation
- diameter of the dispensing hole inconsistent with the order
- impaired head weld to the body
- contamination or scratches visible to the naked eye from a distance of about 30 cm, in dispersed daylight;

cap:

- cap incompatible with the approved sample
- colors not matching the sample (more than 2 hues)
- contamination or scratches visible from a distance of about 30 cm, in dispersed daylight

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print and hot stamping:


- print incompatible with the approved design and sample
- (misalignment) screen print shifted by more than 1 mm
- hot stamping shifted by more than 1 mm
- print not resistant to adhesive tape test
- print not resistant to use
- colors not matching the template up to ± 2 hues

varnish

- lack of varnish
- varnish not resistant to adhesive tape test
- varnish not resistant to use

4.2.2. Acceptable defects (non-compliances):


- discrepancy in tube or cap print color and tube or cap coloration in the range of ± 1 hue
- spot loss of varnish
- spot varnish thickening
- minor scratches inside and/or outside of the tube body.
- order fulfillment at the level of + 10%/- 5% in relation to the quantity ordered
- (misalignment) offset print shifted by more than 0.5 mm

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4.3. Procedures for quality control of raw materials and components


All raw materials and components used in the manufacturing process should be inspected so as to make it impossible to use ones inappropriate or inconsistent with the order. The inspection procedures are described in the table below:

code	subject of the study	test method	who	frequency
RAW MATERIALS				
S1	compliance with the order	checking documents	KJ	every shipment
S2	cleanliness	visual assessment	KJ	every shipment
S3	dampness	touch assessment	KJ	every shipment
DYES				
B1	compliance with the order	checking documents	KJ	every shipment
B2	quality certificate	checking	KJ	every shipment
B3	cleanliness	visual assessment	KJ	every shipment
CAPS				
N1	quality certificate	checking	KJ	every shipment
N2	color compliance	visual assessment, comparison with the template	KJ	every shipment
N3	screwing	checking	KJ	every shipment
N4	cleanliness	visual assessment	KJ	every shipment
N5	flip-top cap	checking	KJ	every shipment
N6	incomplete injection	visual assessment	KJ	every shipment
N7	stalk	visual assessment	KJ	every shipment
N8	injection point	visual assessment	KJ	every shipment


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4.4. Interoperational control procedures

code	subject of the study	test method	who, frequency
TUBE MANUFACTURE			
E1,01	mixture composition	reading data from the mixer's control panel	operator: at the start of production, and every 3 hours during production
E2,01	wall thickness	caliper measurement	operator: 4 pieces per hour
E3,01	pipe length	caliper measurement	operator: 4 pieces per hour
E4,01	pipe inner diameter	checking with a standard pin	operator: 4 pieces per hour
E5,05	surface	visual assessment and smoothness check	operator: 4 pieces per hour
E6,06	coloration	visual assessment, comparison with the sample	operator: 4 pieces per hour
CAPPER			
G1	tube length	caliper measurement	operator: 4 pieces per hour
G2	head coloration	visual assessment, comparison with the sample	operator: 4 pieces per hour
G3	diameter of the dispensing hole	caliper measurement	operator: 4 pieces per hour
G4	thread	visual assessment, screwing on the cap	operator: 2 pieces per hour
G5	weld quality	tear	operator: 2 pieces per hour

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PRINT			
OF1 SD1	print compliance with the sample	visual assessment	operator: 4 pieces per 0.5 hour packers: every tube
OF2 SD3	correct positioning and alignment of the print	comparison with the sample and the design	operator: 4 pieces per 0.5 hour
OF3 SD3	print colors	visual assessment, comparison with the sample	operator: 4 pieces per 0.5 hour packers: every tube
OF4 SD4	correct positioning of varnished surface	visual assessment, comparison with the sample	operator: 4 pieces per 0.5 hour
OF5 SD5	varnish surface	visual assessment	operator: 4 pieces per 0.5 hour packers: every tube
OF6 SD6	print adhesion	checking with self-adhesive tape	operator: 4 pieces per 0.5 hour
HOT STAMPING			
HS1	print compatible with the design	visual assessment	operator: 4 pieces per hour packers: every tube
HS2	correct positioning of the print	comparison with the template	operator: 4 pieces per hour
HS3	foil color compatible with the design	visual assessment, comparison with the sample	operator: 4 pieces per hour packers: every tube
HS4	foil quality	visual assessment	operator: 4 pieces per hour packers: every tube
HS5	print adhesion	checking with self-adhesive tape	operator: 4 pieces per hour

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PACKING			
P1	the right number of tubes in the box	checking	packers: the whole batch
P2	cleanliness	visual assessment	packers: the whole batch
P3	screwing the tubes	visual assessment	packers: the whole batch
P4	tightening the cap	checking	packers: the whole batch
P5	lining the box with a plastic bag and appropriate overlapping of the bag's edges	visual assessment	packers: the whole batch
P6	label	validation of data	packers: the whole batch
P7	the right number of boxes on the pallet	re-count	packers: the whole batch warehouseman: the whole batch

4.5. Acceptance check of finished products

The acceptance check is carried out in accordance with PN-ISO 2859-1 **Sampling procedures for inspection by attributes. Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection** in line with the following assumptions:


- a.** single-step plan,
- b.** general level of control II,
- c.** acceptable quality limit (AQL):
 - for critical non-compliances (defects) AQL = 0.4,
 - for acceptable non-compliances (defects) AQL = 1.5;
- d.** types of inspection:
 - normal,
 - tightened,
 - complete.

The following points are followed in order to determine the compliance of the batch with the established requirements:

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4.5.1. Description of the test

Subject of the study	Test method
<u>packing:</u> <ul style="list-style-type: none"> ➤ the right number of boxes on the pallet ➤ label prepared correctly ➤ correct overlapping of the loose ends of the bag ➤ lining the box with a plastic bag ➤ the right number of tubes in the box ➤ cleanliness ➤ screwing the tubes ➤ tightening the caps 	re-count checking check, visual assessment checking re-count visual assessment visual assessment checking
<u>tube shape</u>	visual assessment, comparison with the template
<u>tube coloration</u>	visual assessment, comparison with the template
<u>tube length</u>	measuring with caliper, visual assessment, comparison with the order or sample
<u>thread</u>	visual inspection, screwing on the cap
<u>tube dispensing hole</u>	measuring with caliper, comparison with the order or sample
<u>print:</u> <ul style="list-style-type: none"> ➤ offset ➤ mesh ➤ HS ➤ unprinted surface ➤ varnish 	visual assessment, ruler measurement, comparison with the sample and the artwork, adhesive tape test
<u>cap:</u> <ul style="list-style-type: none"> ➤ color compliance ➤ correct opening of FT 	comparison with the sample

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4.5.2. Sampling

The sample is taken at random using the "blind method", according to PN-83/N-03010, and in quantities specified in PN-ISO 2859-1.

4.5.3. Inspection scheme


a. Test plan for normal inspection

Critical non-compliances (defects), AQL=0.4, general level of control II

production size	code	sample size	qualifying number (Ac)	disqualifying number (Re)
1,201 – 3,200	K	125	1	2
3,201 – 10,000	L	200	2	3
10,001 – 35,000	M	315	3	4
35,001 – 150,000	N	500	5	6
150,001 – 500,000	P	800	7	8
500 001 - more	Q	1250	10	11

Allowable non-compliances (defects), AQL=1.5, general level of control II

production size	code	sample size	qualifying number (Ac)	disqualifying number (Re)
1,201 – 3,200	K	125	5	6
3,201 – 10,000	L	200	7	8
10,001 – 35,000	M	315	10	11
35,001 – 150,000	N	500	14	15
150,001 – 500,000	P	800	21	22
500 001 - more	Q	1250	21	22

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b. Test plan for tightened inspection

Critical non-compliances (defects), AQL=0.4, general level of control II


production size	code	sample size	qualifying number (Ac)	disqualifying number (Re)
1,201 – 3,200	K	125	0	1
3,201 – 10,000	L	200	1	2
10,001 – 35,000	M	315	2	3
35,001 – 150,000	N	500	3	4
150,001 – 500,000	P	800	5	6
500,001 - more	Q	1250	8	9

Allowable non-compliances (defects), AQL=1.5, general level of control II

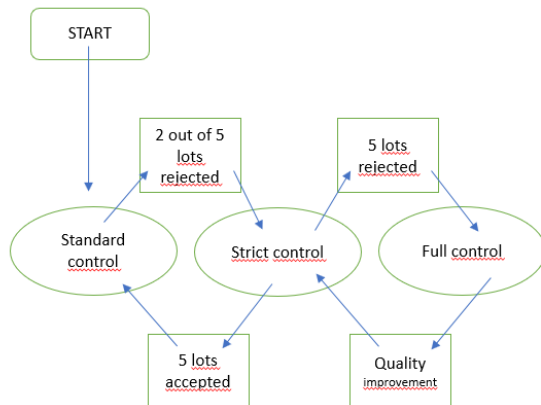
production size	code	sample size	qualifying number (Ac)	disqualifying number (Re)
1,201 – 3,200	K	125	3	4
3,201 – 10,000	L	200	5	6
10,001 – 35,000	M	315	8	9
35,001 – 150,000	N	500	12	13
150,001 – 500,000	P	800	18	19
500,001 - more	Q	1250	18	19

c. Test plan for complete inspection

Complete control provides for inspecting 100% of the batch

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d. Diagram of transition conditions




POCZĄTEK	BEGINNING
a. Kontrola normalna	Standard control
b. Kontrola obostrzona	Strict control
c. Kontrola całkowita	Full control
2 z 5 kolejnych partii nie przyjęto	2 out of 5 consecutive batches not accepted
5 kolejnych partii nie przyjęto	5 consecutive parties not accepted
5 kolejnych partii przyjęto	5 consecutive parties accepted
Produkcja poprawia jakość	Production improves quality

5. COMPLAINTS

In the event of a dispute between the Parties concerning the quality of a delivered batch, the sample signed by the Parties shall be decisive. **CAUTION!** The product involved with the complaint should be in its original packaging. The complaint shall not cover the goods previously filled with the customer's bulk, unless these are hidden defects.

5.1. Notification

Written notification about the non-conformity of the received batch of tubes should be sent to DAFO PLASTICS by fax or e-mail, and then by mail,

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within 14 business days from the date of the item's dispatch from the DAFO PLASTICS warehouse, based on the delivery note.

5.2. Warning

Dafo Plastics shall not be responsible for incorrect settings or bad tooling of the machine sealing the tubes, as a result of which there is the phenomenon of delaminating the tube seal. It is responsible, however, for bad welding of the tube's cylindrical part with the conical part

Reporting non-compliance should contain the following elements:

1. Customer's name and address,
2. Name and surname of the person submitting, telephone number, e-mail,
3. Tube name / cap type and diameter,
4. Customer order no. / internal production number,
5. Batch receipt date / invoice number,
6. Quantity of the batch received (pcs),
7. Quantity of the samples taken for examination (pcs),
8. Quantity of questionable tubes in the collected batch (pcs).


5.3. Checking

In the event of receiving the notification referred to in item 5.1., DAFO PLASTICS reserves the right to:

- a. carry out - with the help of its employees or persons it appoints - a verifying check where the tubes subject to the complaint are stored, or
- b. receive back the batch subject to complaint in full. The returned tubes should be packed the same way as when shipped from DAFO, in original boxes, and the return transport conditions should comply with the provisions of item 3.1.

6.3. Costs

Unless the Parties agree otherwise, if the complaint is accepted, DAFO undertakes to refund the cost of return transport.

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6. FINAL REMARKS


All data and information provided to the Customer by DAFO Plastics SA. are based on the current knowledge and previous experience. Due to the variety and the number of factors that may affect the scope and possibility of using the tubes, as well as the changing knowledge, they do not absolve the Customer from carrying out its own research and clarifications.

Before purchasing a DAFO PLASTICS product, customers and other users should assess whether the product is suitable for the intended use. This document does not constitute a warranty, express or implied, nor does it guarantee the product's suitability for any particular purpose. Unless otherwise agreed in writing, the only compensation for any claims is the replacement of the product or refund of the purchase price, at the discretion of DAFO PLASTICS.

Under no circumstances shall DAFO PLASTICS be liable for any special or indirect losses, fines or exemplary damages.

The data and information provided to the Customer by DAFO Plastics SA cannot - unless explicitly indicated by DAFO Plastics SA- be used to derive legal assurance on the existence of certain properties of tubes or the tubes' suitability for a particular purpose.

In every case the Customer should at their own responsibility and by Customer's own means follow the legal regulations in force.

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7. RELATED DOCUMENTS


- PN-ISO 2859-1 *Sampling procedures for inspection by attributes. Part 1: Sampling schemes indexed by acceptance quality limit (AQL) for lot-by-lot inspection.*
- PN-83/N-03010 *Statistical quality control - random sampling*
- PN-EN ISO 9001:2001
- DAFO Book of quality

8. APPENDICES

8.1. Order form

8.2. Reporting non-compliance

8.3. Product Sheet Template

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9. CHANGES SHEET

Replaces the document		dated			
Changes made					
Changes made by	Name and surname	Date		signature	
Developed by:					
Name and surname	Tomasz Lipina	Bogdan Placek	Andrzej Paszkowski	Izabela Chowaniec	Lucyna Bargieł
Confirmed:	Wojciech Bargieł	Date	Signature		