

1 (3).

PRODUCT SPECIFICATION.

Publisher:	Date:	Publication:	Art No:	Product Name:
Bengt-Inge Brodén	2001-01-15.	1.	10 0002.	UNI-BAG.
Producer:	Responsible Production:	Responsible Quality:	Owner of the Product:	Supplier:
Fristad Plast AB (Fp)	Nicklas Forsström.	Cristian Forsström.	CAS AB	CAS AB

Plastic Bag:

Material.	Polyeten plastic bag, LDPE, white colour.
Length.	Out part welding. 320mm \pm 5mm.
Wide.	Out part welding area. 183mm \pm 5mm.
Thickness.	0.10mm \pm 0.01mm.
Print.	In accordance to given sample.
Colour print.	Speedflex EMS No. 3-05.
Trace-ability.	Lot no. Printed between CE and LDPE triangle see encl. sample.

Membrane:

Material.	Cut into the printed part of the plastic bag and in cooperation with the injection moulded receiver which is welded on the plastic bag.
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Receiver of Funnel:

Material.	Injection moulded Polyeten HDPE.
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Funnel:

Material.	Injection moulded Polyeten HDPE. The direction of the funnels handle, adjustable in accordance to the Need from the patient, otherwise upwards – top of the bag - is Recommended.
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Clean Analytical System AB

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Publisher:	Date:	Publication:	Art No:
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Packing / Wrapping:

Material. Unbleached carton with an inside plastic bag made of transparent Polyeten.

Carton Size:

Outer measure length. 405mm.
Outer measure width. 305 mm.
Outer measure height. 405 mm.

Pieces per Carton. 50 Pcs.
Each level of the pallet contains. 8 Cartons
Number of levels / pallet. 5.
Number of cartons / pallet. 40 Cartons.

LOT mark Trace ability:

Lot mark each carton contain. Year Month Day Time, example 990920 11.39.

Production:

Routines. In accordance to **ISO 9001.**
Test methods. See next page.

Environment:

Routines. In accordance to **ISO 14001.**

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The machinery gives a signal irregularly in order to inform the operator to take samples for control. Three samples shall be taken and receive control marks with date and alarm time.

Example; 04 03 15 11.39.

Year Month Day Time

Sample no 1; Test of air leakage (pneumatic test).

Sample no 2; Pressure test, Drop/Fall test and Hang up test.

Sample no 3; No tests, store the unit under a period of six month for eventually tests.

Instruction pneumatic test.



1. Blow up the bag and check that the welding is intact after that the bag has explored.
- If the welding part is damaged, routine for divergent products shall be established.

Instruction drop/fall test.



2. Connect the Funnel to the P/UNI-BAG and thereafter fill with water, 1 500ml 37° C.
3. Make sure that the floor is cleansed and free from sharp particles; drop the unit to the floor from high-level minimum 1m.
4. Make notes of the result into the test protocol.
- If the unit gets destroyed, routine for divergent products shall be established.

Instruction pressure test.



5. Keep the volume of water in the unit, place the unit at a cleansed table thereafter press the unit repeatedly. Pressure minimum 5 Kg.
6. Make notes of the result into the test protocol.
- If the unit gets destroyed, routine for divergent products shall be established.

Instruction hangs up test.



7. Keep the volume of water in the unit, hang up the unit in its funnels handle under a period of 48 h. Thereafter check the handle of the funnel and the welded area of the bags funnel receiver.
8. Make notes of the result into the test protocol.
- If the unit gets destroyed, routine for divergent products shall be established.

Described Document

Quality Control P-BAG, P-BAG SAP/UNI-BAG.

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