



Product Code : PROBCOVER33	Orig.Date: 12 Sept 10	Spec Ref: PPS- PROBCOVER33	Rev: 02
Style : PROBCOVER33	Rev Date: 10 Jan 13	Page 1 of 6	
Supplier product code :			

Originated By : Ngho Ying Lee Revised By : Wong Kah Mun Manufacturing Location: Karex, Malaysia Supply Code: DT HTS# : NA	Approved By (Marketing) : Manuela Mettlen Approved By (Technical) : Artwork # : SHWB01000
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Reference standard	
Manufacturing compliance	ISO 13485:2003
Condom reference standard	ISO 4074
510(k) number	NA
Product features	
Shape	Parallel (Straight Shaft)
Texture	Smooth (No reservoir)
Color	Natural
Dimension(Length/Width/Thickness), mm	L=Min 195mm, W=52±2mm; wall thickness=0.10±0.05mm, Drip thickness: 0.17mm (max)
Foiled pack dimension (mm)	55 x 55 mm
Lubricant/Qty	None Lubricated
Lubricant flavor	None
Remark : Powder level (min)	40 – 60mg
Strip Length	3 (Remarks: The strip length is 171±1mm of individual foiled condom for 3 pc)
Shelf life	5 years
Printing on film (Bottom foil)	Ansell Probe cover Lot no EXP : YYYY-MM
Quantity per case	2800 pcs – 20 gross
Master Case Label Information	As per below section 12
Additional Pkg Instructions	<ul style="list-style-type: none"> ▪ No split lots between shipments (Lot must be shipped in its entirety). ▪ 3 foiled/strip ▪ 48 strips/inner ▪ 3 x 48 strips = 144 pcs/inner ▪ 20 inners/shipper carton

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Style : PROBCOVER33	Rev Date: 10 Jan 13	Page 2 of 6	
Supplier product code :			

Formulations		
Components	Chemical name	Trade name
Natural Rubber latex	Poly Isoprene	HR Revultex / Givul HR
Corn Starch	-	Absorbo KR
Magnesium Carbonate	-	Magnesium Carbonate – Gold Star

PACKAGING MATERIALS	MATERIAL	DIMENSIONS	FEATURES
FILM (top)	Aluminum	55mm	PK02530 (Sealing type: Square 4 sides)
FILM (bottom)	Aluminum	55mm	PK02548 (Sealing type: Square 4 sides)
Master PolyBag		NA	
Inner		237mm x 175mm x 58mm	
Carton / shipper	T150/M/T150 (DW)	495mm x 370mm x 310mm	Approximate 9.5kg/carton
User Instruction /Leaflet			

11 SPECIAL REQUIREMENTS / MISCELLANEOUS

- Certificate of Analysis to accompany products shipped to US & Canada for CMDCAS compliance purposes
- Other remarks: COA every lots for shipment t be sent to Sourcing QA

12 ARTWORK & LABELING - FOIL

Bottom – Transparent foil

Attached is the sample for quality & position of injection text on actual sample for reference.

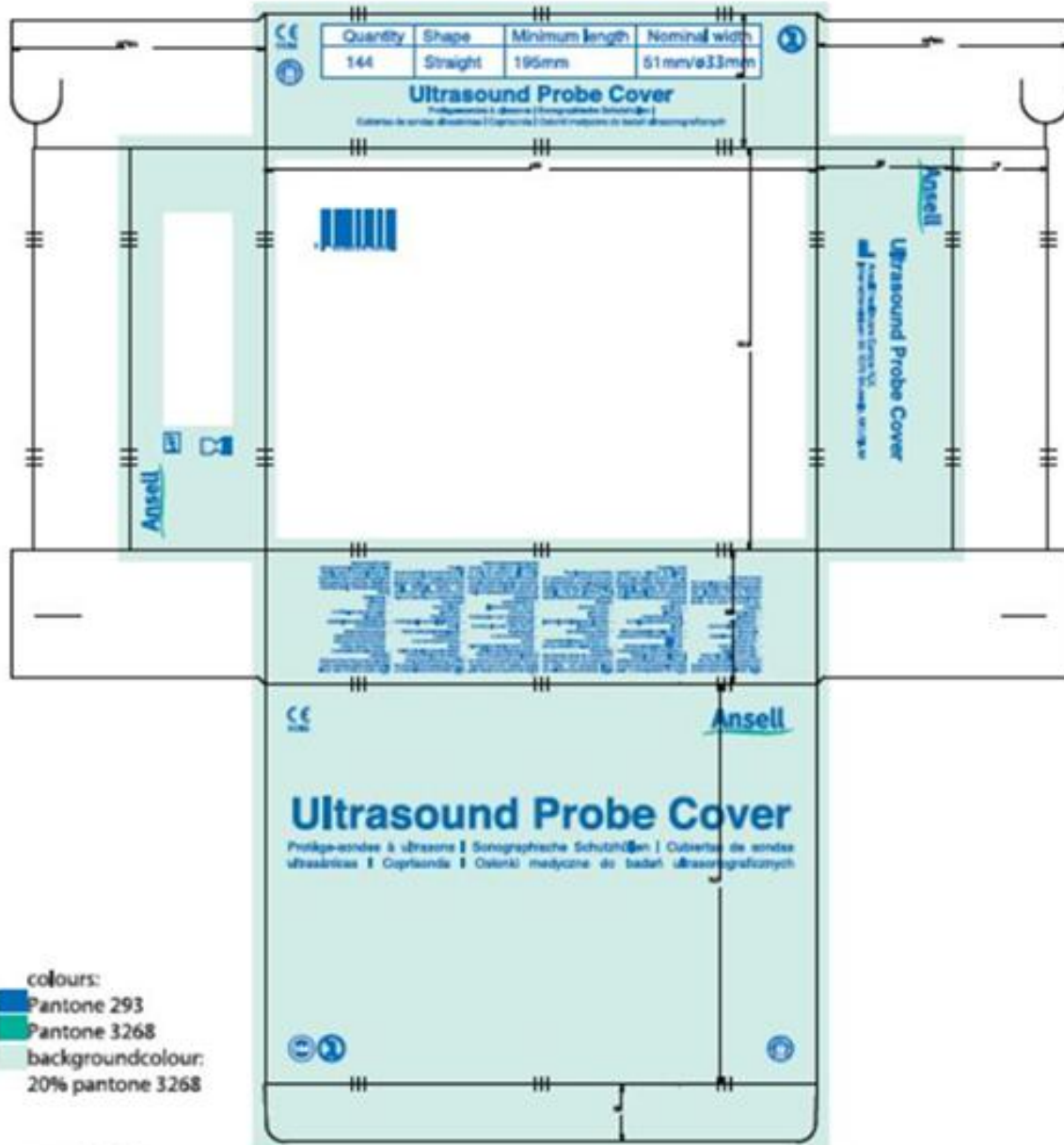


Printing



Product Code : PROBCOVER33	Orig.Date: 12 Sept 10	Spec Ref: PPS-PROBCOVER33	Rev: 02
Style : PROBCOVER33	Rev Date: 10 Jan 13	Page 3 of 6	
Supplier product code :			

12 ARTWORK & LABELING – INNERBOX ARTWORK



colours:
 Pantone 293
 Pantone 3268
 backgroundcolour:
 20% pantone 3268

august 2010

Product Code : PROBCOVER33	Orig.Date: 12 Sept 10	Spec Ref: PPS-PROBCOVER33	Rev: 02
Style : PROBCOVER33	Rev Date: 10 Jan 13	Page 4 of 6	
Supplier product code :			

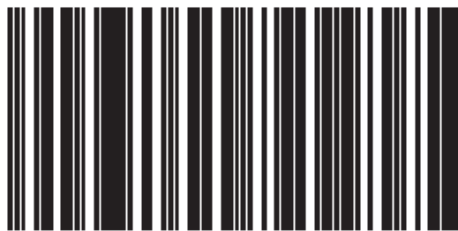
12 ARTWORK & LABELING – INSTRUCTION LEAFLET

NA

12 ARTWORK & LABELING – SHIPPER /CARTON LABEL -

KAREX: ANSELL 51 / Ø33mm (LOT12P018 2017-02) D: 102x152mm 15.1.13 BLACK

Probe Cover 51mm / Ø 33mm



05011831085710

Ansell

20 x 144 pc

LOT 12P018

2017-02



Protège - sondes à ultrasons Sonographische Schutzhüllen
 Cubiertas de sondas ultrasónicas Coprisonda Osłonki medyczne do badań ultrasonograficznych

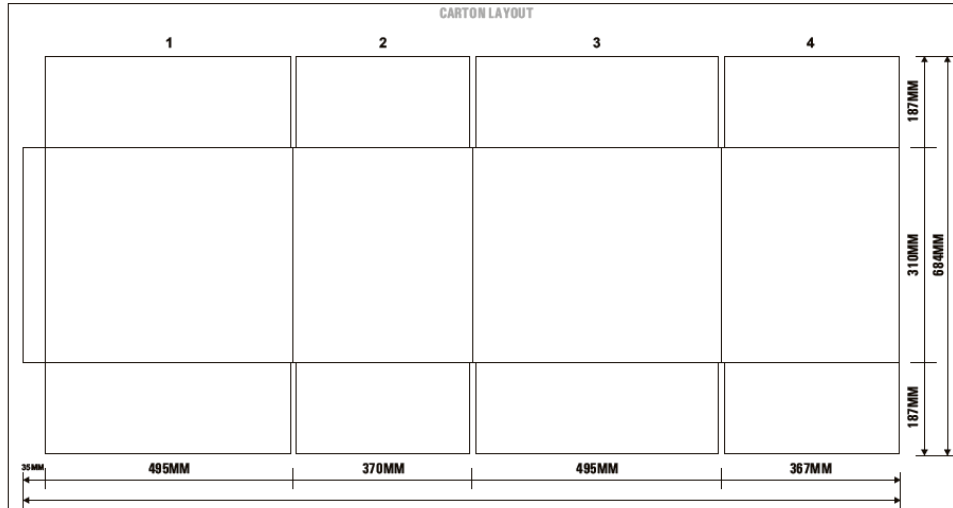
This product is made from natural rubber latex which may cause an allergic reaction

Ansell Healthcare Europe N.V.
 Internationalelaan 55 1070 Brussels, BELGIUM

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Style : PROBCOVER33	Rev Date: 10 Jan 13	Page 5 of 6	
Supplier product code :			

12 ARTWORK & LABELING – SHIPPER /CARTON ARTWORK

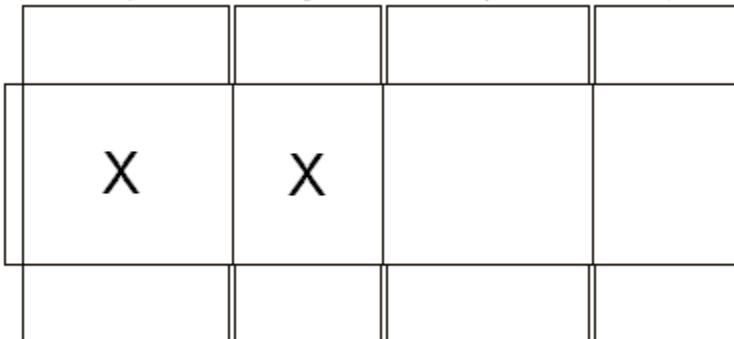


 FOHMAY PAPER PRODUCTS SDN BHD 99, JALAN KEMAS, KEMAS, SEREMBAN, NEGERI SEMBILAN, 70300	CUSTOMER : KAREX INDUSTRIES SDN. BHD.	SUBSTANCE : T150(M)/T150 (D/W)	PREPARED BY	CHECKED BY	APPROVED BY
	DESCRIPTION : RSC (T.1537)	FINISHING : GLUE	SCALE : NIL	70x	
	MEAS: INT. :	COLOUR :	REMARKS :	29/08/2012	

MEAS: EXT. : 495 X 370 X 310 MM

*KAREX11537

Position of shipper label:



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Style : PROBCOVER33	Rev Date: 10 Jan 13	Page 6 of 6	
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REVISION LOG	REQUESTOR	DATE
Rev 0 : New Specification, TBA on shipper carton, foil dimension, material, packing mode, artwork and labeling. Revised to Probcover 35 TBA on shipper carton.	Ngoh Ying Lee	12 September 10 8 October 2010 12 October 2010
Rev 1: Quantity of shipper change from 50 gross to 20 gross. Updated shipper dimension and shipper label	Ho Hui Ying	2 July 2012
Rev 2: Revised on inner box and shipper label address.	Wong Kah Mun	10 Jan 2013

THIS SPECIFICATION AND/OR THE SUBJECT MATTER IS RESTRICTED SOLELY FOR THE USE OF ANSELL AND GLOBAL SOURCING.
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