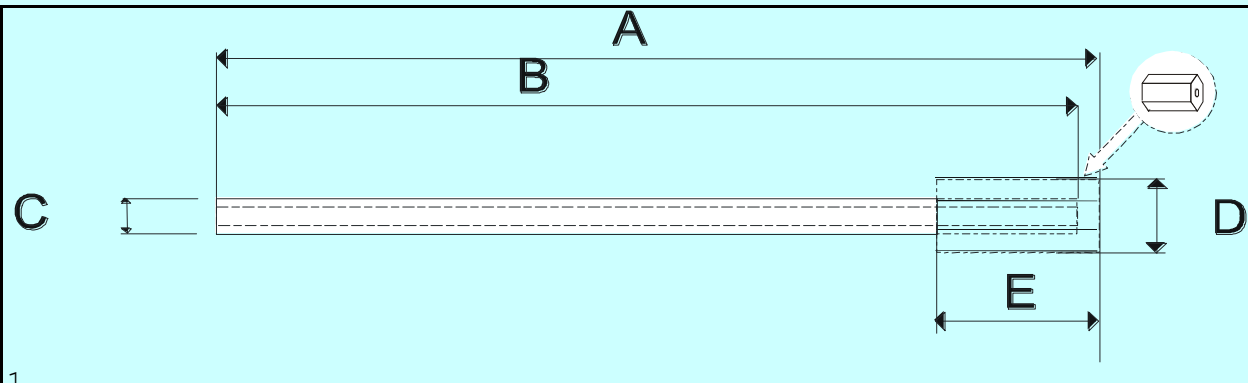
	Dansu A/S Sandbakken 1-3, 3660 Stenløse dansu@dansu.com Tel: 0045 48 18 12 74 Fax: 0045 48 18 31 86	Doc # : Technical documentation Part A/ applicator Rev : 2 PAGE:1/2
	REF. Directives 93/42 EEC Subject Product Data for product number: 12-1168	Sterile: <input type="checkbox"/> Non sterile <input checked="" type="checkbox"/>

Revision	Date	Description of change
1	29.09.14	Second edition
2	11.11.15	Update of measurements


I- Product Description & Classification

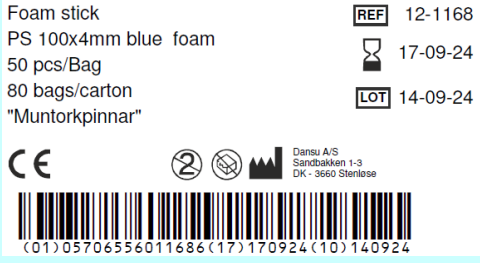
I/1	Name:	<i>PS Applicator 100x4mm, Blue foam head, non-sterile, 50 pcs/bag</i>		
I/2	General description:	<i>Single use PS applicator with hexagonal blue foam head, 50 pcs/plastic bag</i>		
I/3	Class	<i>I non-sterile, rules 4 and 5</i>		
I/4				
I/5	Design:	Dimensions Applicator:	Measurement A,	102 +/-1mm
		Dimensions Stick:	Measurement B Measurement C	92 +/-1mm 3.9 +/-0.1 mm
		Dimensions Head:	Measurement D Measurement E	18 +/-2mm mm 23 mm+/-2mm
		Dimensions primary packaging: plastic bag	Length Width	400 +/-5mm 300 +/-5mm
		Dimensions shipment packaging: carton	No. 1150: 410x460x500mm	

II- Description of use and operating of device

II/1	Application :	- Gentle Mouth hygiene & Teeth cleaning - Superficial wound care
II/2	Intended user:	<i>Professional medical staff</i>
II/3	Medical conditions:	<i>Not applicable</i>
II/4	Instruction of use:	<i>N.A.</i>
II/5	Handling and storage:	<i>Keep in original closed packaging in normal conditions</i>

File Name	Author	Date of release - Edition	Approved / Signature	
PRODUCT DATA 12-1168 non sterile,rev2	SAD	29.09.14 /	Management	Internal control

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III- Composition		
III/1	Composed raw material:	Stick : white Polystyrene choc, round
		Head: 100% Polyurethan (Blue foam) - latex-free, straight-sided hexagon, absorption capacity: 0.6-0.7 g water
		Fixation: Hot melt adherence, no detachment by contact of the water, and primary Glue
III/2	Incorporating non viable materials of animal origins:	Not applicable
III/3	Device incorporating a medicinal substance:	Not applicable
III/4	REACH relevant components:	The product is exempt from registration with REACH (Directive EC 1907/2006) - is phthalate-free and free of dangerous substances as per the ECHA list.
III/5	Cytotoxicity / Skin irritation	The product shows no cytotoxic or skin irritating effects (ISO 10993-5, 10993-10)
IV- Special consideration		
IV/1	Special requirement for use:	The foam can be decontaminated with ETO on customer's request
V- Methods of manufacturing		
V/1	Type of manufacturing	Assembling manually. Fixation of head with glue and heat melting system. No detachment up to 10 N.
V/2	Primary packaging:	Bag Soft, transparent PE 40 micron Customer's logo can be printed on request
		Number per package: 50 pcs/bag
V/3	Shipment packaging:	Carton Corrugate carton
		Number per package: 80 bags per carton
		Weight Number per Pallet: 12 cartons per pallet
V/4	Labelling: <ul style="list-style-type: none"> Name and address of manufacturer : Name /description of product: Article no: Quantity : LOT no : Indication for single use: Year of manufacturing: 	
V/5	Environment	Harmless
VI- Description of use in combination with other devices		
VI/1	Not applicable	

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