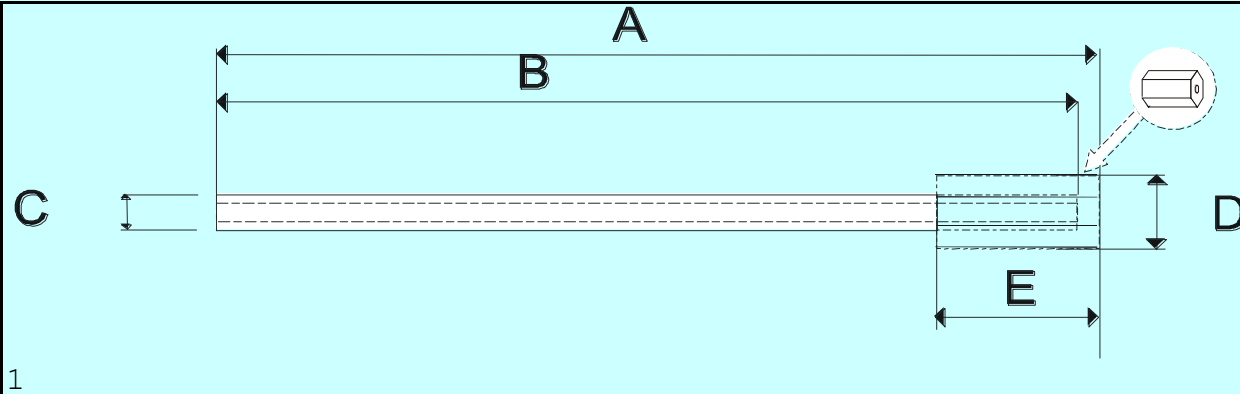

	Dansu A/S Sandbakken 1-3, 3660 Stenløse dansu@dansu.com Tel: 0045 48 18 12 74 Fax: 0045 48 18 31 86		Doc # : Technical documentation Part A/ applicator Rev : 1 PAGE:1/2	
	REF. Directives 93/42 EEC		Subject Product Data for product number: 12-1156	
		Sterile: <input type="checkbox"/>		
		Non sterile <input checked="" type="checkbox"/>		

Revision	Date	Description of change
1	12.05.14	Second edition

I- Product Description & Classification				
I/1	Name:	PS Applicator 150x4mm, Green foam head, non-sterile, 5 pcs/bag		
I/2	General description:	Single use PS applicator with hexagonal green foam head, 5 pcs/plastic bag		
I/3	Class	I non-sterile, rules 4 and 5		
I/4				
I/5	Design:	Dimensions Applicator:	Measurement A,	150 +/-2mm
		Dimensions Stick:	Measurement B Measurement C	140 +/-1mm 4 +/-0.1 mm
		Dimensions Head:	Measurement D Measurement E	18 +/-2mm mm 25 mm +/-2mm
		Dimensions primary packaging: plastic bag	Length Width	230 +/-2mm 100 +/-2mm
		Dimensions shipment packaging: carton	No. 822: 200x200x285mm	
II- Description of use and operating of device				
II/1	Application :	- Gentle Mouth hygiene & Teeth cleaning - Superficial wound care		
II/2	Intended user:	Professional medical staff		
II/3	Medical conditions:	Not applicable		
II/4	Instruction of use:	N.A.		
II/5	Handling and storage:	Keep in original closed packaging in normal conditions		

III- Composition

File Name	Author	Date of release - Edition	Approved / Signature	
PRODUCT DATA 12-1156 non sterile	SAD	26.09.14 /	Management	Internal control





	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 : 1 PAGE:2/2
	REF. Directives 93/42 EEC		Subject Product Data for product number: 12-1156
		Sterile: <input type="checkbox"/>	Non sterile <input checked="" type="checkbox"/>

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 OPP 25 micron
		Number per package:	Customer's logo can be printed on request
V/3	Shipment packaging:	Carton	Corrugate carton
		Number per package:	50 bags per carton
		Weight	
		Number per Pallet:	290 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: 		
		<div> <div>Green Foam stick 150x4mm</div> <div>PS Choc sticks</div> <div>Bag 5 pcs</div> <div>50 bags/carton</div> </div> <div> <div>REF 12-1156</div> <div>17-09-26</div> <div>LOT 14-09-26</div> </div> <div> <div>CE</div> <div>    </div> <div> Dansu A/S Sandbakken 1-3 DK - 3660 Stenløse </div> <div>  <div>(01)05706556011563(17)170926(10)140926</div> </div> </div>	

V/5	Environment	Harmless
-----	-------------	----------

VI- Description of use in combination with other devices

VI/1	Not applicable
------	----------------

File Name	Author	Date of release - Edition	Approved / Signature	
PRODUCT DATA 12-1156 non sterile	SAD	26.09.14 /	Management	Internal control