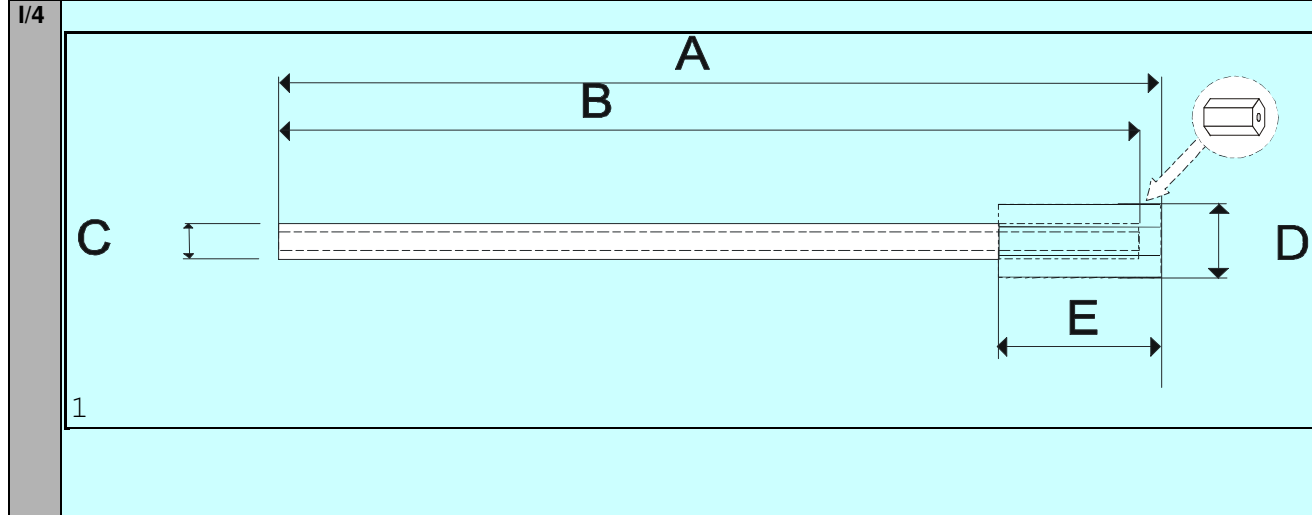
	Dansu A/S Sandbakken 1-3, 3660 Stenløse dansu@dansu.com Tel: 0045 48 18 12 74 Fax: 0045 48 18 31 86	Doc # : Technical documentation Part A/ applicator Rev : 2 PAGE:1/2
	Regulatory Ref. Regulation (EU) 2017/745 (MDR)	Subject Product Data for product number: 12-1166

Revision	Date	Description of change
1	12.05.14	Second edition
2	17.01.22	Third edition

I- Product Description & Classification

I/1	Name:	<i>PS Applicator 150x4mm, Blue foam head, non-sterile, 5 pcs/bag</i>
I/2	General description:	<i>Single use PS applicator with hexagonal blue foam head, 5 pcs/plastic bag</i>
I/3	Class	<i>I non-sterile, rules 4 and 5 of Annex VIII of Regulation (EU) 2017/745</i>




I/5	Design:	Dimensions Applicator:	Measurement A,	150 +/-2mm
		Dimensions Stick:	Measurement B	140 +/-1mm
			Measurement C	4 +/-0.1 mm
		Dimensions Head:	Measurement D	18 +/-2mm mm
			Measurement E	25 mm +/-2mm
Dimensions primary packaging: plastic bag	Length Width	200 +/-2mm 95 +/-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:	<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 12-1166 non sterile_MDR.doc	SAD	17.01.2022_V2	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
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:	Should not be used with Alcohol. Compatibility with the following substances has been demonstrated: - Water - Hydrogen Peroxide (3%) - Betadine - Octenisept - Eosine - Merfen

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: 5 pcs/bag
V/3	Shipment packaging:	Carton Corrugate carton
		Number per package: 50 bags per carton
		Weight Number per Pallet: 290 cartons per pallet
V/4	<u>Labelling:</u> <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: 	Blue Foam Stick 150x4mm REF 12-1166 PS Choc sticks  2026-08 Bags of 5 pcs LOT 21.06.08 50 bags/carton      Dansu A/S Sandbakken 1-3 DK - 3660 Stenløse MD   (01)25706556011666(17)260600(10)210608

VI- Description of use in combination with other devices	
VI/1	Not applicable

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