

REF: Regulation (EU) 2017/745 (MDR)

Subject: **Product Data** for product number:  
**12-1168**

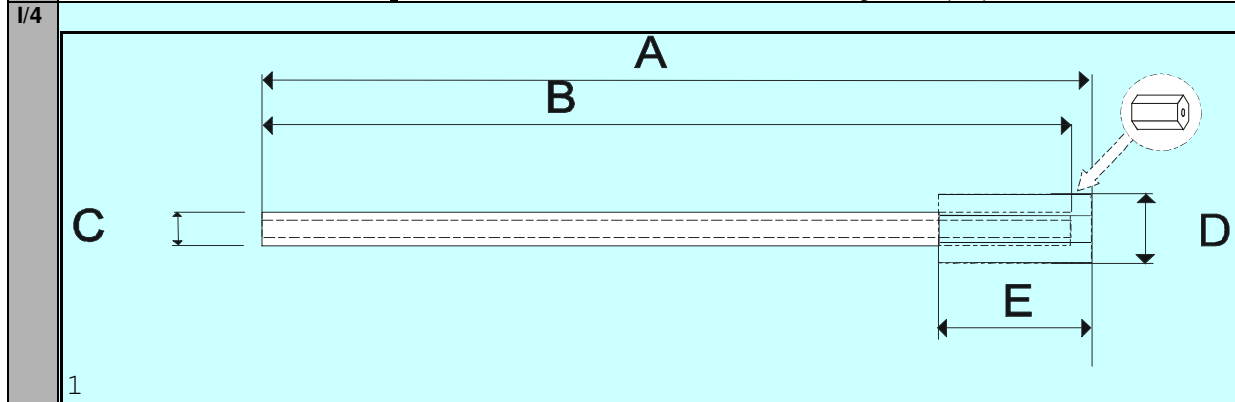
Sterile:

Non sterile:

Revision	Date	Description of change
1	29.09.14	Second edition
2	11.11.15	Update of measurements
3	17.01.22	Fourth edition

### 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 of Annex VIII of Regulation (EU) 2017/745</i>




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	255 +/-5mm 350 +/-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:	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

File Name	Author	Date of release - Edition	Approved / Signature	
PRODUCT DATA 12-1168 non sterile_MDR.doc	SAD	17.01.2022_V3	Management	Internal control

	<b>Dansu A/S</b> 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 : 3  PAGE:2/2
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### III- Composition

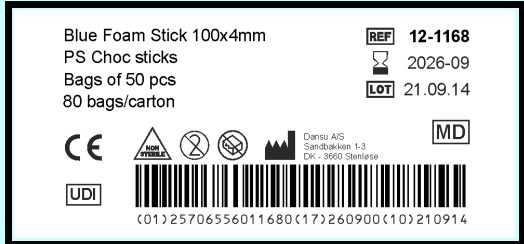
III/1	Composed raw material:	<b>Stick :</b>	white Polystyrene choc, round
		<b>Head:</b>	100% Polyurethan (Blue foam) - latex-free, straight-sided hexagon, absorption capacity: 0.6-0.7 g water
		<b>Fixation:</b>	Hot melt adherence, no detachment by contact of the water, and primary Glue
III/2	Incorporating 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:	Should not be used with Alcohol.  Compatibility with the following substances has been demonstrated: - Water - Hydrogen Peroxide (3%) - Betadine - Octenisept - Eosine - Merfen
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### 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	<b>Labelling:</b> <ul style="list-style-type: none"> <li>Name and address of manufacturer :</li> <li>Name /description of product:</li> <li>Article no:</li> <li>Quantity :</li> <li>LOT no :</li> <li>Indication for single use:</li> <li>Year of manufacturing:</li> </ul>	
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### VI- Description of use in combination with other devices

VI/1	Not applicable
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