


PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	Wood Applicator
I/2	General Description	Applicator with Wooden Stick, 150x2.5 mm, Big Cotton head, Continental Shape
I/3	GMDN N°	33954
I/4	Reference Number	1021275
I/5	Class	<input checked="" type="checkbox"/> I <input type="checkbox"/> Is <input type="checkbox"/> IIa According to Annex VIII of the Regulation 2017/745 (MDR), Rules 4 and 5
I/6	Notify Body	CE
I/7	Composition Raw Material	100% cotton (head) and Wooden Stick
I/8	Sterile	<input type="checkbox"/> Yes <input checked="" type="checkbox"/> No If, yes <input type="checkbox"/> ETO <input type="checkbox"/> Gamma <input type="checkbox"/> Steam
I/9	First Packaging	Number of pieces in Packaging: 50 pieces per pouch
I/10	Picture	

II- Description of use and operating of device		
II/1	Intended use/indication:	A device intended used to apply a substance (eg medication) to the Ear/Nose/throat (ENT) treatment and to care the superficial wound for absorption, barrier or compressing. Alone, single use and transient use (<60min)
II/2	User:	Medical staff or professional
II/3	Contraindication of use	Not use, if the device is dirty or visual defects If packaging is damaged or open do not use.
II/4	Special requirement for use	Warning: fragile product (can break). Handle with Care Should not be use with Alcohol
II/5	Handling and storage conditions:	Standard conditions or atmospheric conditions

