



PRODUCT DATA

I-Product Description & Classification		
I/1	Designation	Examination Gloves
I/2	General Description	The gloves with paper, size S/M/L, length 275mm, thickness 25µm
I/3	GMDN N°	34020
I/4	Reference Number	3109113 (S) / 3109114 (M) / 3109115 (L)
I/5	Class	<input type="checkbox"/> I <input checked="" type="checkbox"/> Is <input type="checkbox"/> IIa According to Directive 93/42/EEC - Annex IX, Rules 5
I/6	Notify Body	CE₀₁₂₃ (legal manufacturer : Hengya Plastics Product Co., Ltd)
I/7	Composition Raw Material	EVA (ethylene-vinyl acetate) + LLDPE (Linear low-density polyethylene) + Paper
I/8	Sterile	<input checked="" type="checkbox"/> Yes <input type="checkbox"/> No If, yes <input checked="" type="checkbox"/> ETO <input type="checkbox"/> Gamma <input type="checkbox"/> Steam
I/9	First Packaging	Number of pieces in Packaging: 1 piece per peel pack
I/10	Intended Use	Examination Gloves with paper can prevent cross infection between the patients and the medical staff or the users in the surgical examination and treatment. Single use.

II- MANUFACTURING		
II/1	Manufacturing Operations	<input checked="" type="checkbox"/> peel pack <input type="checkbox"/> pouches <input checked="" type="checkbox"/> boxes <input checked="" type="checkbox"/> cartons <input type="checkbox"/> cleaning <input checked="" type="checkbox"/> sterilization
		1 pieces per peel pack 100 peel pack per box 10 box per cartons
II/2	<u>Labelling: According to Directive 93/42/EEC Annex I and EN980</u> <ul style="list-style-type: none"> Name and description of product Name and address of manufacturer Name and address of distributor Name and address of EU representative LOT N° Article N° Expiry date Quantity Sterile Method of sterilisation Indication for single use Not use if the pack is opened Latex free CE 0123 	Example of a label
II/3	Place of sterilisation:	By Zhangjiagang Huagiang Sterilization Co
II/4	EU representative	By Shanghai International Holding Corp. Gr Effestrasse 80, D-20537 Hamburg
II/5	Distributor	By Applimed SA