



## E.A.R.-CERTIFICATE



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## **Annex A - List of Devices**

(Article 9, section 1 of the Directive 93/42/EEC on medical devices)

#	Catalogue reference number	Commercial Name	Generic Device Term	Short description and intended use	GMDN Code	Class	Rule
1.	LEGPPS	Powdered  Latex  Examination  Gloves	Natural White,  Powdered, Smooth,  Ambidextrous, Non	Non Sterile, Ambidextrous, Made by Natural Rubber. Use by healthcare personnel. Worn over hands as a biological barrier.	NA	I	5
2.	LEGPFT	Powder Free  Latex  Examination  Gloves	Natural White, Powder Free, Textured, Ambidextrous, Non Sterile	Non Sterile, Ambidextrous, Made by Natural Rubber. Use by healthcare personnel. Worn over hands as a biological barrier.	NA	I	5
3.	NTPF	Nitrile Gloves	Blue/White/Black, Powder Free, Textured, Ambidextrous, Non Sterile	Non Sterile, Ambidextrous, Made by Synthetic Rubber. Use by healthcare personnel. Worn over hands as a biological barrier.	CEN NA	I	5
4.	SURPPT	Sterile Pre- Powdered  Latex Surgical  Gloves	Natural White, Powdered, Textured, Hand Specific, Sterile	Sterile, Hand Specific Shape, Made by Natural Rubber. The device is to provide biological protection (Barrier protection and cross- contamination) both to the wearer and patient during medical use. The gloves are worn in the hands by the medical personnel during clinical practice.	NA	IIA	7

5.	SURPFT	Sterile Powder  Free Latex	Natural White, Powder Free, Textured, Hand Specific, Sterile	Sterile, Hand Specific Shape, Made by Natural Rubber. The device is to provide biological protection (Barrier protection and cross- contamination) both to the wearer and patient during medical use. The gloves are worn in the hands by the medical personnel	NA	IIA	7
		Surgical Gloves	TED RE	during clinical practice.			

