

Job Description & Specification

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Project:				
Requested By				
Name / Position				
Address				
Telephone No				
Origination Date				
Device Class: I : Iia : Iib: III				
		Description/Performance	Specification/ Comment	Predicted Risks
1		Intended Use		
		General specification		
	a	Height		
	b	Width		
	c	Depth		
	d	Weight		
2		Power Requirements		
	a	AC/DC		
	b	Voltage		
	c	Frequency		
	d	Wattage Normal		
	e	Wattage at swith on mode		
	f	Wattage in sleep mode		
	g	Battery specification		
	h	Battery life		
	i	Battery size		
	j	Battery type		
3		Physical		
	a	Colour		
	b	Material		
	c	Visual acuity		
	d	Mounting		
4		Display		
	a	Accuracy		
	b	Resolution		
	c	Usage continuous Y / N		
	d	Calibration		
	e	User controls		
	f	Stability		
	g	Response time		
	h	External conditions affecting accuracy		
5		Alarms		
6		Accessories		
7		Desired Appropriate Standards		
	a	IEC 606.01 EMC		

	b	IEC 606-02 EMC		
	c	IEC 601 Safety		
	d	MDD Essential Requirements		
	e			
	f			
	g			
8		Final Design Tests Required		
	a	In-house		
	b	External		
	c	3 rd Party testing		
	d	Special Tests		
9		Acceptance test Criteria		
10		Trial Requirements		
		Clinical trials		
11		Maintenance		
	a	Manual		
	b	On-site		
	c	Return to base		
	d	Overseas sales		
	e	Lifespan		
12		Software		
		Repeatability		
		Reliability		
13		Packaging		
	a	Breakage		
	b	Contamination		
	c	Storage conditions		
14		Accessories		
	a	Detachable components		
	b	Sterile /Single use		
15		Environment		
	a	Vibration		
	b	Noise		
	c	Radiation		
	d	Magnetic		
	e	Electrostatic		
	f	EMC IN / out		
	g	Heat		
	h	Flame		
	i	Latex		
	j	Volume		
	k	Pressure		
	l	Electric shock		
	m	Ingress of moisture		
	n	Ingress of dust		
	o	Cross infection		
	p	Frequency of patient exposure		
	q	Duration of patient exposure		
	r	Current Technology used		
	s	Construction		
	t	Current medical practices		
	u	Health & safety of patient		
	v	Health & safety of user		

	w	Intended use		
	x	Possible misuse		
	y	Possible side effects		
	z	Ergonomical features		
	aa	Ease of use		
	bb	Blood products		
	cc	Animal products		
	dd	Sterile /Single use		
	ee	Mechanical stability		
	ff	Gas supplies		
	gg	Hydrolic supplies		
	hh	Calibration		
	ii	Ageing		
	jj	Flow rates		
	kk	Reaction with other equipment		
	ll	Reciprocal interference		
	mm	Operating temperature		
	nn	Storage temperature		
	oo	Operating altitude		
	pp	Storage altitude		
	qq	Operating Relative Humidity		
	rr	Storage Relative Humidity		
	ss	Waterproofing /spill resistance		
	tt	Cleaning and disinfection		
	uu	Disposal of product		
16		Notified Body required Y/N		
17		User manual		
	a	Cleaning		
	b	Intended purpose		
18		Clinical Benefit/Risk		
QC 22				