## PRE-PURCHASE QUESTIONNAIRE

## EXTENDED FORM PPQ – June 2003

# Produced by NHS Purchasing and Supply Agency, Scottish Healthcare Supplies, Northern Ireland CSA Regional Supplies Service and Welsh Health Supplies in conjunction with the Association of British Healthcare Industries

This form is intended to supply prospective purchasers with information about equipment being considered for purchase. It is intended principally for pre-purchase information on electrical medical, dental, ophthalmic and laboratory equipment. The form may also be used for other products, including non-electrical items, and to give information prior to equipment being supplied on loan, in which case not all the questions will be relevant. Please ensure all relevant questions are answered.

For i	ssue c	and completion	ı by purchaser:	PPQ Maste	er Reference:								
A unique reference (preferably ten characters maximum) must be given by the supplier: Supplier's Reference: 0895													
Generic Device Type: Ventilator Equipment Model: Nippy 3+													
Coun	ntry of	Origin:	England		Manufa	cturer:	B and D I	Electromedi	cal				
Supp	lier:		B and D Ele	ctromedical		Telepho	ne No:	01789 29	3460				
Fax 1	No:		01789 2624	70		e-mail:		quality@nippyventila			n		
CE M	ARK	ING											
1.	a)	Does the proc	luct carry the CE	marking?						YES	X	NO	
	b)	If YES, to wh	nich EC Directive	e(s):							LI		LI
		i) Active	Implantable Me	dical Devices	Directive (90/3	85/EEC)				YES			
		ii) Medica	al Devices Direct	tive (93/42/EE	C)					YES	Х		
		If YES	, state classificat	ion of device	(93/42/EEC An	nex IX)					2b		
iii) In Vitro Diagnostic Medical Devices Directive (98/79/EC)						YES							
	If YES, is the device: For self-testing? YES Covered by Annex II: List A? YES List B?					YES		NO					
For ii) and iii) above, Identification No. of Notified Body, if applicable						(	0086						
		iv) EMC I	Directive (89/336	EEC or super	rseding directiv	e))				YES			
v) Low Voltage Directive (73/23/EEC)							YES						
	vi) Other Directive(s) (please specify)												
2.	a)	Is the product	t a 'custom-made	e device' (93/4	2/EEC)?					YES		NO	Х
	b)	Is the product	t intended for 'cli	inical investig	ation' (93/42/E	EC) or 'performa	nce evaluatio	on' (98/79/EC)	?	YES		NO	Х
		If YES to a) o	or b) above, does	the device con	mply with the U	JK Medical Devi	ces Regulatio	ons?		YES		NO	
MANA	MANAGEMENT SYSTEM STANDARDS												
3.	a)	Is the manufa	cturer currently	registered to a	ny managemen	t system standard	s (eg ISO 90	01, ISO 14001	, ISO 13485)?	YES	Х	NO	
		If YES, pleas	e state the standa	urd(s) and certi	ification body:	ISO 13485,	BSI						
	b)	Is the supplie	r's service and re	pair organisat	ion currently re	gistered to any n	anagement s	ystem standard	ls?	YES	Х	NO	
		If YES, pleas	e state the standa	ard(s) and certi	ification body:	ISO 13485,	BSI						•
SAFE'	TY S	<b>FANDARDS</b>											
4.	For p	roducts not CE	E marked to 1 b)	l), ii) or iii) ab	ove, with which	n safety standard	s) does the p	roduct comply	?				

Standard	Test House	Certificate Number	Date	

#### SERVICE / SPARES / INSTALLATION

5. Is service/re	pair information available?	YES X	X NO If NOT f.o.c	. please state cu	Irrent price Indicate conten	ts below:			
(Please state	Full circuit diagrams	YES	Fault finding procedure	YES	Preventative maintenance	YES			
YES, NO or N/A)	Repair information	YES	Spare parts listing YES		List of special tools/test equipment/etc N/A				
If YES, please state whether also available on: Disk Website If Web, please state address									

### 6. a) In addition to the service/repair information/manual, will training be required before competent technical personnel can provide:

	(Please state YES, NO or N/A)	First-line maintenance	YES		Calibration	YES
		Planned preventative maintenance YES			Repair	YES
b)	<ul> <li>b) Is the supplier able to provide this training for the purchaser's or a third party's technical personnel?</li> <li>If YES, will this be free of charge? NO Or chargeable? YES</li> </ul>				YES X	NO
	If NO, please indicate if details o	vailable on request?	YES	NO		

<ul> <li>Is the provision of service-repair information conditional upon completion of training?</li> <li>In order to indentity understanding of special understanding explorment/boling required?</li> <li>YTS, please indicate that dealls of special understanding explorment/boling required better.</li> <li>YTS, please indicate that dealls of special understanding explorment/boling are provided on a separate sheet.</li> <li>If requirs are unreally performed by the anglifer on the gurths where the UK?</li> <li>If requirs are unreally performed by the anglifer on the gurths where sheet.</li> <li>If requirs are unreal by performed by the anglifer on the gurths where sheet.</li> <li>If requirs are unreal by performed by the anglifer on the gurths where sheet.</li> <li>If requirs are unreal by performed by the anglifer on the gurths where sheet.</li> <li>If requirs are unreal by performed by the anglifer on the gurths where sheet.</li> <li>If requirs are unreal by the training of the gurths are unreal by the sheet sheet.</li> <li>If requirs are unreal by the training anglifer on the gurth shubby trained and equipped personal:</li> <li>YES NO NO</li></ul>				Supplier's Reference:	08	95			
a) In order to underdate maintenance repair/additionality interventes equipment/tooling required?       YES       NO       X         7. a) Is the supplier able to provide a non-acterized information exercise in the UK?       YES       NO       X         10) Is the supplier able to provide a non-acter pair/maintenance service in the UK?       YES       NO       X         11) Is the supplier able to provide a non-acter pair/maintenance service in the UK?       YES       NO       X         11) If repairs are normality performed by the supplice note parthaser's state to pilot response time:       YES       NO       X         12) If repairs are normality performed by the supplice note parthaser's its places tatter typical personnet:       YES       NO       X         13) Is free of charge toom equipment normally variable?       YES       O       X         2007       If repairs an ormality and typical pairs atter typical pairs atteratypical pairs atter typical pairs atter typical pairs									
If YTS, place indicate that details of special softwaretes equipment tooling are provided on a separate sheet:       YTS       YTS       NO         7.       a) Is the supplier able to provide an commer reprintimizance service in the UK?       YTS       NO       X         9) Is the supplier able to provide a commer reprintimizance service in the UK?       YTS       NO       X         11       YTS, place confirm that details of reprintimizance service in the UK?       YTS       NO       X         10) If trepsia are performed by the supplier on the purchaser's site, places state typical reproses time:       Image: State Stat		,							
7. a) Is the supplier able to provide an 'as equired expair/indimension service' If USC       YES       NO       X         9. Is the supplier able to provide a conner repair/indimension covervice' If YES, please confirm that details of repair/indimension covervice' If YES, please state trippic an ensemption of a first parts' and neuronal time:       YES       NO       X         9. If trippic and neuronally performed by the supplier on the partsbards' site that the please state trippic an ensemption of the partsbard' is on a first parts' is an table trippic of expanse.       YES       NO       X         8. Please state if repair parts conditional upon acquisition of repair information?       YTS       Or mining?       YTS       NO       X         9. Please indicate when this model was first placed on the market:       INO       INO       X       X       XO       X         10. Will software upgrade parts conditional upon acquisition of repair information?       VTS       NO       X         9. Please indicate when this model was first placed on the market:       INO       INO       X         11. Is installation measury?       MTS       NO       X         12. Will software upgrades to solidity?       NO       INO       X         13. Will software upgrades to actilize radiation or is it capable of equiring ionising radiation?       YES       NO       X         12. Will software upgrades to actilize radiation or is it cap		d)				NO X			
b)       Is the supplier able to provide a contact regularization accessor service?       YES       NO       X         If YES, please confirm that dealls of regular constructions are provided on a separate sheet.       YES       NO       X         10       If require an enormality performed by the supplier on the purchaser's site, please state: typical response time:       IVES       NO       X         110       Is feed charge load enopinpoint anomally area supplied in the purchaser's or a third party's suitable trained and equipped personnel:       YES       NO       X         9.       Please state if reprir parts will be available to the purchaser's or a third party's suitable trained and equipped personnel:       YES       NO       X         9.       Please indicate sheen this model was first placed on the market:       2007       X       X       NO       X         9.       Please indicate sheen this model was first placed on the market:       2007       X       X       NO       X         10.       a) for how rany years from the date of last arrandictare is the supply of sparse parts guaranitee?       YES       NO       X         11.       bit interpolets the notified?       NO       YES       NO       X         12.       Will software upgrades to notified?       NO       X       YES       NO       X         13.			If YES, please indicate that details of special software/test equipment/tooling are provided	d on a separate sheet:	YES				
If YES, please confirm that details of repair maintenance contracts are provided on a separate sheet.          i) If repairs are anomally performed by the supplice on the purchaser's site, please state cypical reproduct in:       iiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiiii	7.	a)	Is the supplier able to provide an 'as required' repair/maintenance service in the UK?		YES X	NO			
c) i) If repairs are normally performed by the supplier on the parchaser's site, please state typical response time:          ii) If repairs are normally performed by the supplier on the parchaser's site, please state typical response time:       Image: Imag		b)	Is the supplier able to provide a contract repair/maintenance service?		YES	NO X			
ii) If repairs are performed off-site, where will these be carried out?       Compasy:       B and D Electromedical       Location:       Stratford on Avon       Typical tuneound time:       1 week         iii) b fee of otherge loss equipment normally available:       Ytsis       NO       X         8. Please state if repair parts will be available to the purchaser's or a third party's suitably trained and equipped personnet:       Ytsis       NO       X         9. Please indicate when this model was first placed on the market:       2007       7       NO       X         10. a) For how many years from the date of late manufacture is the supply of space parts guaranteed?       YES       NO       X         11. Is installation accessary?       If YES, justee confirm that details of all services required are provided on a separate sheet:       YES       NO       X         12. Will software upgrades be notified?       NA       YES       NO       X         DECONTANTION REPROCESSING         14. a) i       Is the item intended to be: Non-settifie for single use       Sterilized       NO       NO       X         ii) If YES, is the time intended to be: Non-settifie for single use       YES       NO       If YO, go to Question 15.         iii) If YES, is the time intended to be: Non-settifie for single use       Sterilized       Other       If NO, go to Question 15.			If YES, please confirm that details of repair/maintenance contracts are provided on a sepa	rate sheet.	YES				
Company:       B and D Electromedical       Location:       Stratford on Avon       Typical turnaround time:       1 week         iii)       Is free of funge four equipment tormally available?       VIS       NO       X         8.       Please state if repair parts will be available to the parchaser's or a hind party's suitably trained and equipped personnet:       VIS       NO       X         9.       Please indicate when this model was first placed on network:       2007       7       NO       X         10.       a) For how many years from the date of last manufacture is the supply of spare parts guaranteed?       7       7       NO       X         11.       Is installation necessary?       YES       NO       X       NO       X         12.       With software upgrades be notified?       N/A       YES       NO       X         INVERS (in blem in intended to be processed?       YES       NO       X         INVERS (in blem in intended to be processed??       YES       NO       X         INVERS (in blem in intended to be processed??       YES       NO       X         INVES (in the inn intended to be processed??       YES       NO       X       If NO, go to Question 15         IF VES (in the inn intended to be processed??		c)	i) If repairs are normally performed by the supplier on the purchaser's site, please stat	e typical response time:					
iii) Is free of charge loan equipment normally available?       YES       NO       X         8. Please state if repair parts will be available to the purchaser's or a third party's suitably trained and equipped personnel:       YES       NO       X         9. Please indicate when this model was first placed on the market:       2007       NO       X         9. Please indicate when this model was first placed on the market:       2007       NO       X         10. a) For how many years from the date of last manufacture is the supply of spare parts guaranteed?       YES       NO       X         11. Is installation necessary?       If NO, indicate year of last manufacture:       YES       NO       X         12. Will software upgrades he notified?       NA       YES       NO       X         DOE the product ontim a source of ionising radiation or is it capable of emiting ionising radiation?       YES       NO       X         DECONTANIMATION / REPROCESSING         13. Does the product ontime and trade to be: Non-sterifie for single ms       Sterilized k       Onter       WES       NO       X         14. a)       1       If NPRO (ESSING       NO       K       WES       NO       X       NO       X         15. Obset the product ontain a source of ionising radiation or is it capable of emuting ionising radiation?       YES <td></td> <td></td> <td>ii) If repairs are performed off-site, where will these be carried out?</td> <td></td> <td></td> <td></td>			ii) If repairs are performed off-site, where will these be carried out?						
8. Please state if repit parts with the available to the purchaser's or a third party's suitably trained and equipped personel: VES NO X 9. Please indicate when this nodel was first placed on the narket: 2007 9. Please indicate when this nodel was first placed on the narket: 2007 10. a) For how many years from the date of last manufacture is the supply of spare parts guaranteed? 7 11. Is installation necessary? 12. With software upgrades be notified? 12. With software upgrades be notified? 13. Dues the product still in current production? YES NO X 14. If NDS, please confirm that details of all services required are provided on a separate sheet: 12. With software upgrades be notified? 13. No & K 14. a) i) Is the tiem intended to be processed/reprocessed? 14. a) i) Is the tiem intended to be roosesed/reprocessed? 15. Sintilated 16. Dues the accountering manuable of sus? 17. YES NO X 18. State item intended to be roosesed/reprocessed? 18. With YES, please state: 19. If YES, is the item intended to be roosesed/reprocessed? 19. NO X 19. If YES, is the item intended to be roosesed/reprocessed? 10. X If YES, please state: 10. If NO, go to Question 15. 11. State item intended to be roosesed/reprocessed? 12. YES NO X 13. What is the maximum turber of use? 14. a) iii for the intended to be roosesed/reprocessed? 15. YES NO 16. If YES, please state 17. YES NO 17. YES NO 28. NO 29. The manual cleaning method specified befree further reprocessing? 18. Who is the maximum temperature that can be used for thermal distinction? 19. Is the manual cleaning the ony cleaning method specified befree further reprocessing? 19. What is the maximum temperature that can be used for thermal distinction? 19. If XES, please state equipment? 19. If XES, please stat			Company: B and D Electromedical Location: Stratford o	n Avon Typical t	urnround time:	1 week			
If YES, is the supply of repair parts conditional upon acquisition of repair information?       YES       Or maining?       YES       NO         9.       Please indicate when this model was first placed on the market:       2007         10.       a) For how many years from the date of last manufacture is the supply of spare parts guaranteed?       7         b) Is the product still in current production?       YES       NO       X         If ND, indicate year of last manufacture:       YES       NO       X         If WES, please confirm that details of all services required are provided on a separate sheet:       YES       NO       X         IONISING RADIATION       IS. Does the product contain a source of ionising radiation or is it capable of emitting ionising radiation?       YES       NO       X         DECONTAMINATION / REPROCESSING       If NO, go to Question 15.         ii) Is the tire intended to be processed/reprocessed?       YES       NO       X       If YES, please state       NO       X         iii) If YFS, is the time intended to be processed/reprocessing?       YES       NO       X       NO       YES       NO       YES       NO       X         10.       Is the time intended to be reprocessing instructions supplieft       YES       NO			iii) Is free of charge loan equipment normally available?		YES	NO X			
If YES, is the supply of repair parts conditional upon acquisition of repair information?       YES       Or maining?       YES       NO       X         9.       Please indicate when this model was first placed on the market:       2007       Z007         10.       a) For how many years from the date of last manufacture is the supply of spare parts guaranteed?       7       T         b) Is the product still in current production?       YES       NO       X       YES       NO       X         11.       Is installation necessary?       YES       NO       X       YES       NO       X         12. Will soltware apgrades be notified?       NA       YES       NO       X         INVESTIG RADIATION         13. Does the product contain a source of ionising radiation or is it capable of emitting ionising radiation?       YES       NO       X         DECONTAMINATION / REPROCESSING         14. a)       i) Is the item intended to be processod/reprocessed?       YES       NO       X       If YES, lease state:       NO       X         iii) If YFS, is the lase intended to be processod/reprocessing?       YES       NO       X       NO       X       NO       X         iii) B the item intended to be reprocessing instructions supplied?       VES       NO       X<	8.	Pleas	se state if repair parts will be available to the purchaser's or a third party's suitably trained a	nd equipped personnel:	YES X	NO			
9. Please indicate when this model was first placed on the market:       2007         10. a) For how many years from the date of last manufacture is the supply of spare parts guaranteed?       7         b) Is the product still in current production? YES NO if If NO, indicate year of last manufacture:       7         11. Is installation necessary?       YES NO if If NO, indicate year of last manufacture:       7         12. Will software upgrades be notified?       NA if YES, please confirm that details of all services required are provided on a separate sheet:       YES NO X         IONSING RADIATION         13. Does the product contain a source of ionising radiation or is it capable of emitting ionising radiation?       YES NO X         DECONTAMINATION / REPROCESSIO         14. a) i) Is the item intended to be proceed/reprocessed?       YES NO X       If NO, go to Question 15.         ii) If YES, is the item intended to be: Non-sterile for single use Sterilized Disinfected Other       Other       If NO, go to Question 15.         iii) Is there a recommended maximum number of uses?       YES NO X       If YES, please state:       TES NO         ii) A the item intended to be: specessing instructions supplied?       YES NO X       YES NO X       TES NO X         iii) What is the maximum temperature that can be used for thermal disinfection?       TES NO X       TES NO X         ii) A re there any restrictions on delaged dispically?       YES									
10. a) For how many years from the date of last manufacture is the supply of spare parts guaranteed?       7         b) Is the product still in current production? YES X NO if I/NO, indicate year of last manufacture:       7         11. Is installation necessary?       YES NO X         If YES, please confirm that details of all services required are provided on a separate sheet:       YES NO X         IONISING RADIATION       NA YES NO X         12. Will software upgrades be notified?       NA YES NO X         DECONTAMINATION / REPROCESSING       NO X         14. a) i) Is the item intended to be: Non-sterile for single use initiation?       YES NO X         Disinfected X       Other       I'NO, go to Question 15.         ii) If YES, is the item intended to be: Non-sterile for single use initiation?       YES NO X       I'NO, go to Question 15.         iii) If YES, is the item intended to be: Non-sterile for single use initiated X of the decontamination/reprocessing instructions supplied?       YES X NO       YES X NO         v) Are instructions available for safe disposal?       YES X NO       YES X NO       YES X NO         ii) What is the maximum number of uses?       YES NO X       I'YES NO X       YES NO X         v) Are instructions available for safe disposal?       YES NO X       YES NO X       YES NO X         v) Are instructions available for safe disposal?       YES NO X       YES NO X									
b) Is the product still in current production? YES X NO       If NO, indicate year of last manufacture:         11. Is installation necessary?       YES X NO       YES X       NO       X         11. Is installation necessary?       YES X       NO       X       YES       NO       X         12. Will software upgrades be notified?       N/A       YES       NO       X         DOES the product contain a source of ionising radiation or is it capable of emitting ionising radiation?       YES       NO       X         DECONTAMINATION (REPROCESSING         14. a)       1       Is the ine intended to be processed/reprocessed?       YES       NO       X         DECONTAMINATION (REPROCESSING         14. a)       1       Is there a monthed to the processed/reprocessed?       YES       NO       If NO, go to Question 15.         DISING exolution available for the single use       Stellized       Other       If NO, go to Question 15.         10       Is there a recommended maximum number of uses?       YES       NO       X       YES       NO<	9.	Pleas	se indicate when this model was first placed on the market:		2	007			
b) Is the product still in current production? YES X NO       If NO, indicate year of last manufacture:         11. Is installation necessary?       YES X NO       YES X       NO       X         11. Is installation necessary?       YES X       NO       X       YES       NO       X         12. Will software upgrades be notified?       N/A       YES       NO       X         DOES the product contain a source of ionising radiation or is it capable of emitting ionising radiation?       YES       NO       X         DECONTAMINATION (REPROCESSING         14. a)       1       Is the ine intended to be processed/reprocessed?       YES       NO       X         DECONTAMINATION (REPROCESSING         14. a)       1       Is there a monthed to the processed/reprocessed?       YES       NO       If NO, go to Question 15.         DISING exolution available for the single use       Stellized       Other       If NO, go to Question 15.         10       Is there a recommended maximum number of uses?       YES       NO       X       YES       NO<	10.	a) F	For how many years from the date of last manufacture is the supply of spare parts guaranteed	1?		7			
11.       Is installation necessary?       YES       NO       X         17       If YES, please confirm that details of all services required are provided on a separate sheet:       YES       NO       X         12.       Will software upgrades be notified?       NA       YES       NO       X         DOUSING RADIATION         13.       Does the product contain a source of ionising radiation or is it capable of emitting ionising radiation?       YES       NO       X         DECONTAMINATION / REPROCESSING         14.       a)       b is the item intended to be processed/reprocessed?       YES       NO       X         If YES, is the item intended to be brocksed/reprocessed?         YES       NO       X       If YES, please state       If NO, go to Question 15.         ii)       for the contamination/reprocessing instructions supplied?       YES       NO       X       If YES, please state         iii)       Are instructions available for safe disposal?       YES       NO       If YES, please       Use Chlorine based or 70% isopropyl         iii)       What is the maximum temperature that can be used for thermal disinfection?       Temp:       n/a         iii)       What is the maximum temperature that can be used for for 3 mins?       YES       NO       x									
If YES, please confirm that details of all services required are provided on a separate sheet:       YES         12. Will software upgrades be notified?       NA       YES       NO         IONISING RADIATION         13. Does the product contain a source of ionising radiation or is it capable of emitting ionising radiation?       YES       NO       X         DECONTAMINATION / REPROCESSING         14. a)       i)       Is the item intended to be: Non-sterik for single use       Sterifized       Disinfacted       Other       If NO, go to Question 15.         ii)       If YES, is the item intended to be: Non-sterik for single use       Sterifized       Disinfacted       Other       If NO, go to Question 15.         iii)       If YES, is the item intended to a spearate sheet:       YES       NO       X       If YES, please state:       If YES, please state:       If YES, please state:       YES       NO       X         ii)       Are there any restrictions on detergent/disinfection f       Temp:       nO       If YES, please       VES       NO       X         iii)       Are there any restrictions on detergent/disinfection f       Temp:       nO       X       If YES, please       VES       NO       X         ii)       Are there any restrictions on detergent/disinfection f       YES       NO       X       If Y									
12. Will software upgrades be notified?       N/A       VES       NO       X         INVA       VES       NO       X         INVA       VES       NO       X         INVESTIGE RADIATION         13. Does the product contain a source of ionising radiation or is it capable of emitting ionising radiation?       VES       NO       X         DECONTAMINATION / REPROCESSION         14. a)       i)       Is the item intended to be: Non-sterile for single use       Sterilized       Disinfected       Other       If NO, go to Question 15.         iii)       If YES, is the item intended to be: Non-sterile for single use       Sterilized       Disinfected       Other       If NO, go to Question 15.         iii)       If there are recommended maximum number of uses?       YES       NO       X       If YES, please state:       If YES, please view       YES       NO       If YES, please       VES       NO       X       NO       X       If YES, please       YES       NO       X       If YES, please       YES       NO       X       X       X       NO       X       If YES, please       YES       NO       X       If YES, please state       YES       NO       X       If YES, please state       YES <t< td=""><td>11.</td><td></td><td></td><td></td><td></td><td>NO X</td></t<>	11.					NO X			
UNISING RADIATION         13. Does the product contain a source of ionising radiation or is it capable of emitting ionising radiation?       YES       NO       X         DECONTAMINATION / REPROCESSING         14. a) i) Is the item intended to be processed/reprocessed?       YES       NO       X       If NOs, go to Question 15.         ii) If YES, is the item intended to be: Non-sterile for single use isterilized in the processing instructions available for safe disposal?       YES       NO       X       If YES, please state:       NO       Y         iii) If sthere a recommended maximum number of uses?       YES       NO       X       If YES, please state:       NO       Y         v) Are instructions available for safe disposal?       YES       NO       TES       X       NO         b) i) Is manual cleaning the only cleaning method specified before further reprocessing?       YES       NO       X         iii) What is the maximum temperature that can be used for thermal disinfection?       Termp:       n/a         iii) Are there any restrictions on detergent/disinfectant types?       YES       NO       X         vi) Does reprocessing require the use of specified equipment?       YES       NO       X         vi) Does reprocessing require the use of specified equipment?       YES       NO       X         vii) If YES, ple		lf YE	ES, please confirm that details of all services required are provided on a separate sheet:		YES				
13. Does the product contain a source of ionising radiation or is it capable of emitting ionising radiation?       YES       NO       X         DECONTAMINATION / REPROCESSING         14. a)       i)       Is the item intended to be processed/reprocessed?       YES       NO       If NO, go to Question 15.         ii)       If YES, is the item intended to be: Non-sterile for single use	12.	Will	software upgrades be notified?	N/A	YES	NO X			
13. Does the product contain a source of ionising radiation or is it capable of emitting ionising radiation?       YES       NO       X         DECONTAMINATION / REPROCESSING         14. a)       i)       Is the item intended to be processed/reprocessed?       YES       NO       X       If NO, go to Question 15.         ii)       If YES, is the item intended to be: Non-sterile for single use       Sterilized       Disinfected       0ther       Image: Colored and the									
DECONTAMINATION / REPROCESSING         14. a)       i)       Is the item intended to be processed/reprocessed?       YES       NO       If NO, go to Question 15.         ii)       If YES, is the item intended to be: Non-sterile for single use       Sterilized       Disinfected       Other				tion?	VES				
14. a)       i)       Is the item intended to be processed?       YES       NO       If NO, go to Question 15.         ii)       If YES, is the item intended to be: Non-sterile for single use       Sterilized       Disinfected       Other         iii)       Is there a recommended maximum number of uses?       YES       NO       If YES, please state:         iv)       Are decontamination/reprocessing instructions supplied?       YES       NO         v)       Are decontamination/reprocessing?       YES       NO         ii)       Is manual cleaning method specified before further reprocessing?       YES       NO         iii)       Are there any restrictions on detergent/disinfectant types?       YES       NO       X         iii)       Are there any restrictions on detergent/disinfectant types?       YES       NO       X         v)       Is the item withstand autoclaving at 137 °C for 3 mins?       YES       NO       X         vi)       Does reprocessing require the us of specified equipment?       YES       NO       X         if YES, please state equipment type (eg containers, processors, etc) and, where appropriate, parameters of operation (eg temp, pressure, etc):       If YES, please state       YES       NO       X         ii)       If YES, are they supplied with the device or available optionally?       Suppli	15.	Does	s the product contain a source of forising radiation of is it capable of emitting forising radia	uon?	IES	NO A			
ii)       If YES, is the item intended to be: Non-sterile for single use       Sterilized       Disinfected       Other         iii)       Is there a recommended maximum number of uses?       YES       NO       X       If YES, please state:         iv)       Are decontamination/reprocessing instructions supplied?       YES       X       NO         v)       Are instructions available for safe disposal?       YES       X       NO         b)       i)       Is manual cleaning the only cleaning method specified before further reprocessing?       YES       X       NO         iii)       Are there any restrictions on detergent/disinfectant types?       YES       X       NO       X         vi)       Can the item withstand autoclaving at 137 °C for 3 mins?       YES       NO       X       YES       NO       X         vi)       Does reprocessing require the use of specified equipment?       YES       NO       X       YES       NO       X         ii)       If YES, please state equipment type (eg containers, processors, etc) and, where appropriate, parameters of operation (eg temp, pressure, etc):       If YES, please state       YES       NO       X         ii)       If YES, are they supplied with the device or available optionally?       Supplied       Optional       Neither         d)	DEC	ONT	AMINATION / REPROCESSING						
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