

A tool to assist the pre-purchase selection process of bespoke contoured seating



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Introduction (1)



- ⌘ What is bespoke contoured seating?
- ⌘ Relevance of the Medical Devices Directive (MDD) and Regulations
- ⌘ The essential requirements
- ⌘ CE marking



Introduction (2)



- ⌘ Risk classification
- ⌘ No requirement for 3rd party audit
- ⌘ Need for tool development
 - ☑ To assist prospective purchasers in choosing a manufacturer



Literature search (1)



- ⌘ Published work scarce
- ⌘ MHRA & PASA pre-purchase questionnaire
- ⌘ Regulatory requirements
- ⌘ Clinical Governance



Literature search (2)



- ⌘ Controls Assurance standards
- ⌘ National, European & International standards
- ⌘ Questionnaire design



Questionnaire realisation (1)

⌘ Question selection

- ☑ Only critical issues included within tool

⌘ Questioning technique

⌘ Scoring system



Questionnaire realisation (2)

	Response level		
	1	2	3
Do the Medical Devices Regulations 2002 apply to the device?	Y	-	N/DK



Questionnaire realisation (2)

	Response level		
	1	2	3
Do the Medical Devices Regulations 2002 apply to the device?	Y	-	N/DK
Do you use a recognised quality management system?	Y	N/DK	-



Questionnaire realisation (2)

	Response level		
	1	2	3
Do the Medical Devices Regulations 2002 apply to the device?	Y	-	N/DK
Do you use a recognised quality management system?	Y	N/DK	-
The device technical file should contain only technical drawings of device components.	Strongly disagree / Disagree	-	Agree / Strongly agree



Validation



⌘ Peer group review

- ☑ Content

- ☑ Science

⌘ Modifications required

- ☑ Reduce length

- ☑ Two stage approach



Pilot study



⌘ Description of sample

- ☑ 16 manufacturers used

- ☑ Both commercial and non-commercial

⌘ Format used



Pilot study - significant results

- ⌘ Medical Devices Regulations not applicable (19%)
- ⌘ No performance specification (50%)
- ⌘ Mis-understanding of the “technical file” (31%)
- ⌘ Narrow views of risk management
- ⌘ Lack of maintenance schedules



Pilot study - significant results

- ⌘ Accreditation to ISO 9001 did not preclude level 3 responses (25%)
- ⌘ Over half (63%) of respondents would not have passed to stage 2
- ⌘ Detail modifications leading to questionnaire finalisation



Discussion (1)



- ⌘ Published work scarce
- ⌘ Literature search highlighted many issues
- ⌘ Standards help demonstrate conformity with the essential requirements
- ⌘ Validation critically informed development prior to pilot phase



Discussion (2)

⌘ Pilot study critical to tool development

- ☑ established suitability of questions

- ☑ outcomes highlighted many issues

 - ☑ would appear to prove requirement for tool

 - ☑ negative outcomes would require clarification

- ☑ identified only detail modifications required prior to finalisation

⌘ Telephone interview informative



Conclusions (1)



- ⌘ Tool proved to inform potential purchasers about manufacturer
- ⌘ Identification of potentially increased risk levels
- ⌘ Provides a basis for discussion on the aspects of manufacture with apparent increased risk



Conclusions (2)



- ⌘ Tool helps demonstrate fulfilment of some requirements of Clinical Governance and Controls Assurance standards
- ⌘ Helps ensure continuity of process for pre-purchase decisions
- ⌘ Applicable to broader base of medical devices due to generalisation



Further work



- ⌘ Tool to be made more widely available
- ⌘ Development of follow on guidelines to assist with more detailed examination of bespoke contoured seating
- ⌘ Development of generalised tool for all medical devices



Acknowledgements



⌘ **Colin Gibson**, Consultant Clinical Engineer, Rookwood Hospital, Cardiff

⌘ **David Calder**, Senior Rehabilitation Engineering Manager, King's College Hospital, London



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