

HERFURTH & PARTNERS



ALLIURIS

Legal Issues and Documentation

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Preface

Basics

Management

Background of Legal Issues

- Legal Framework of EU-Directives
- National Statutory Law
- Case Law on National Statutory Law
- Contracts between consumers and distributors
- Contracts between distributors and manufacturers
- Individual analysis of the legal framework necessary



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Basics

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Customer Requirements

- Individual requirements of the consumers
- Installation instructions
- Product descriptions
- Circumstances of the contract conclusion
- Interface: contract management and documentation



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Loss of Marketability

- Documentation cannot compensate poor design
- Remaining risks have to be minimized with warnings
- Documentation is essential for hazardous prevention
- Health and Safety Regulations: prevention of hazards
- Blocking entry of risky products into market



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Responsibility of the Companies

- Product Liability is the manufacturer's liability
- Health and Safety Regulations address the manufacture
- Documentation is prepared by technical writers
- Management is liable for the internal organisation
- Selection and instruction of the technical writers



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Translation of Documentation

- Documentation must be comprehensible
- Using language that is understood by the readers
- Adjustments to local customs



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Review of Legal Requirements

- Legal requirements are different
- Product, area of distribution, target user group
- Research of legal requirements
- Update of the legal requirements



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Risk Analyses

- Avoid potential product hazards in the design
- Risk Analyses during the design
- Use of the Risk Analyses to prepare the documentation
- Use of other relevant information



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Effective Warnings

- To see and to get the warning
- Highlight warnings with safety graphics
- Prioritise the warnings
- Include product misuse



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Monitoring of Documentation

- Ensure that Documentation is kept up-to-date
- Monitor compliance with current developments



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International Distribution

- Worldwide use of products
- Different use expectations
- Contractual obligations
- Monitoring system

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