Recommendations by the Quality Task Group (27): Packaging Systems

When it came to processing medical devices little attention was paid for a long time to sterile supply packing. The psychological sense of security conferred by the visible presence of packaging was more important than the actual requirements and the underlying process. Neither the correct choice of ➜ **PACKAGING** nor the consequences of inadequate packaging warranted much reflection.

➜ Little atrtention has been paid up to now to the **TYPES OF PACKAGING**

The Quality Task Group, a working group composed of experts, is now dealing with this topic. Its goal is to give users an easily understood ➜ **GUIDE**, presented in tabulated form, to enable them to assign the different types of packaging to their respective standards as well as to evaluate them in economic terms.

➜ **GUIDE** enables a normative classification

Safety aspects and ➜ **USER FRIENDLINESS** are also taken into consideration. Particular attention is also paid to validation. This is because in view of the markedly more stringent quality requirements (see ISO 17664), anywhere in the world, each manufacturer of medical devices, each hospital as well as anyone dealing with medical device packaging and sterilisation must focus in detail on this aspect of quality management.

➜ **USER FRIENDLINESS** and safety aspects are taken into consideration

In the context of standard ISO 11607, validation is understood to mean *"the provision of documented proof that all quality requirements addressed to the process are fulfilled and that the process repeatedly produces devices that meet the given specifications"*.

As far as the packing process is concerned, this means that the process must be ➜ **REPRODUCIBLE**. Processes that unfold differently on each occasion do not lend themselves to validation.

➜ The packaging process must be **REPRODUCIBLE**

Binding procedural directives and standard operating procedures, as stipulated by a quality management system, as well as specialist personnel who undergo regular training are a prerequisite for ➜ **VALIDABLE PROCESSES**.

➜ For **VALIDABLE PROCESSES** standard operating procedures as stipulated by a QM system are a prerequesite

These recommendations are divided into three parts:

Part 1: Soft Packaging Systems
Part 2: Hard Packaging Systems and
Part 3: Comparison of the Systems

By consulting the tables, the user should be able to select the appropriate system

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Table 1a: Soft packaging systems

		Transparent package					Paper bags		
		Bags			Tubes/Rollen				
		self-sealable	heat-sealable with gusset	heat-sealable without gusset	heat-sealable with gusset	heat-sealable without gusset	self-sealable	heat-sealable with gusset	heat-sealable without gusset
Packaging material									
Competent standards	DIN	replaced by EN 868-5	replaced by EN 868-5	replaced by EN 868-5	replaced by EN 868-5	replaced by EN 868-5	replaced by EN 868-5	replaced by EN 868-5	replaced by EN 868-5
	EN	868-5	868-5	868-5	868-5	868-5	868-4	868-4	868-4
	ISO	11607[2]	11607[2]	11607[2]	11607[2]	11607[2]	11607[2]	11607[2]	11607[2]
Packaging technique									
	manually	X					X		
	mechanically		X	X	X	X		X	X
Validation									
reproducible		no[1]	yes	yes	yes	yes	no[1]	yes	yes
validable		no[1]	yes	yes	yes	yes	no[1]	yes	yes
Application technology									
Competent standards	DIN		58953-7	58953-7	58953-7	58953-7		58953-7	58953-7
	EN								
	ISO	11607[2]	11607[2]	11607[2]	11607[2]	11607[2]	11607[2]	11607[2]	11607[2]
Methods of sterilization									
steam		yes	yes	yes	yes	yes	yes	yes	yes
formaldehyde		yes	yes	yes	yes	yes	yes	yes	yes
ethylene oxide		yes	yes	yes	yes	yes	yes	yes	yes
gas plasma		no	no	no	no	no	no	no	no
hot air		no	no	no	no	no	no	no	no
liquid media		no	no	no	no	no	no	no	no
Economic efficiancy									
Investment material		high	high	average	average	average	high	high	high
Investment equipment		not any	high	high	high	high	not any	high	high
Working time		average	average	low	average	low	high	average	low

[1]no suitable validation procedure momentarily known (MPBetreibV)
[2]includes no specific informations for the operator
[3]a separate workplace is recommended

Table 1b: Soft packaging systems

		Wrapping sheets					PE bags (e.g. TYVEK)		
			woven		nonwoven		bags		tubes/Rollen
		Cotton	Microfibre	Canvas, mixed	Fleece	Paper	self-sealable	heat-sealable without gusset	heat-sealable without gusset
Packaging material									
Competent standards	DIN	not compliant to standard	replaced by EN 868-5	replaced by EN 868-5	replaced by EN 868-5	replaced by EN 868-5			
	EN	not compliant to standard	868-2	868-2	868-2	868-2	868-9 und 868-10	868-9 und 868-10	868-9 und 868-10
	ISO	not compliant to standard	11607[2]	11607[2]	11607[2]	11607[2]	11607[2]	11607[2]	11607[2]
Packaging technique									
	manually	X	X	X	X	X	X		
	mechanically							X	X
Validation									
reproducible		no[1]	no[1]	no[1]	no[1]	no[1]	no[1]	yes	yes
validable		no[1]	no[1]	no[1]	no[1]	no[1]	no[1]	yes	yes
Application technology									
Competent standards	DIN				58953-7	58953-10		58953-7	58953-7
	EN								
	ISO	11607[2]	11607[2]	11607[2]	11607[2]	11607[2]	11607[2]	11607[2]	11607[2]
Methods of sterilization									
steam		yes	yes	yes	yes	yes	no	no	no
formaldehyde		yes	yes	yes	yes	yes	yes	yes	yes
ethylene oxide		yes	yes	yes	yes	yes	yes	yes	yes
gas plasma		no	no	no	no	no	yes	yes	yes
hot air		no	no	no	no	no	no	no	no
liquid media		no	no	no	no	no	no	no	no
Economic efficiancy									
Investment material		high	high	high	high	average	high	high	high
Investment equipment		not any	not any	not any	not any	not any	not any	high[3]	high[3]
Working time		high	high	high	high	high	high	low	low

[1]no suitable validation procedure momentarily known (MPBetreibV)
[2]includes no specific informations for the operator
[3]a separate workplace is recommended