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World Federation for Hospital Sterilisation Sciences

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Société Suisse de Stérilisation Hospitalière
Società Svizzera di Sterilizzazione Ospedaliera

THE REQUIREMENTS OF SWISS GOOD PRACTICE: RISK AND QUALITY MANAGEMENT

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INTRODUCTION

The Swiss Good Reprocessing Practices for Medical Devices :

- Reference manual for Swiss hospitals and third-party reprocessing providers for hospitals
- Guidelines for the correct operation of a reprocessing service

INTRODUCTION

- Editeur : Swissmedic
- Developed by: Swissmedic, SSSH and SSHH

The supervisory authority Swissmedic (art. 76, para. 1 ODim) uses this book as a basis for inspections of the reprocessing of medical devices in hospitals.

HISTORY

- 1st version in April 2004, completed in November 2005
  - Result of the Swissnoso CJD-Task Force
  - Swissmedic, SSSH and SSHH collaboration (Swiss recommendations, **not related to Creutzfeldt-Jakob disease transmission**)

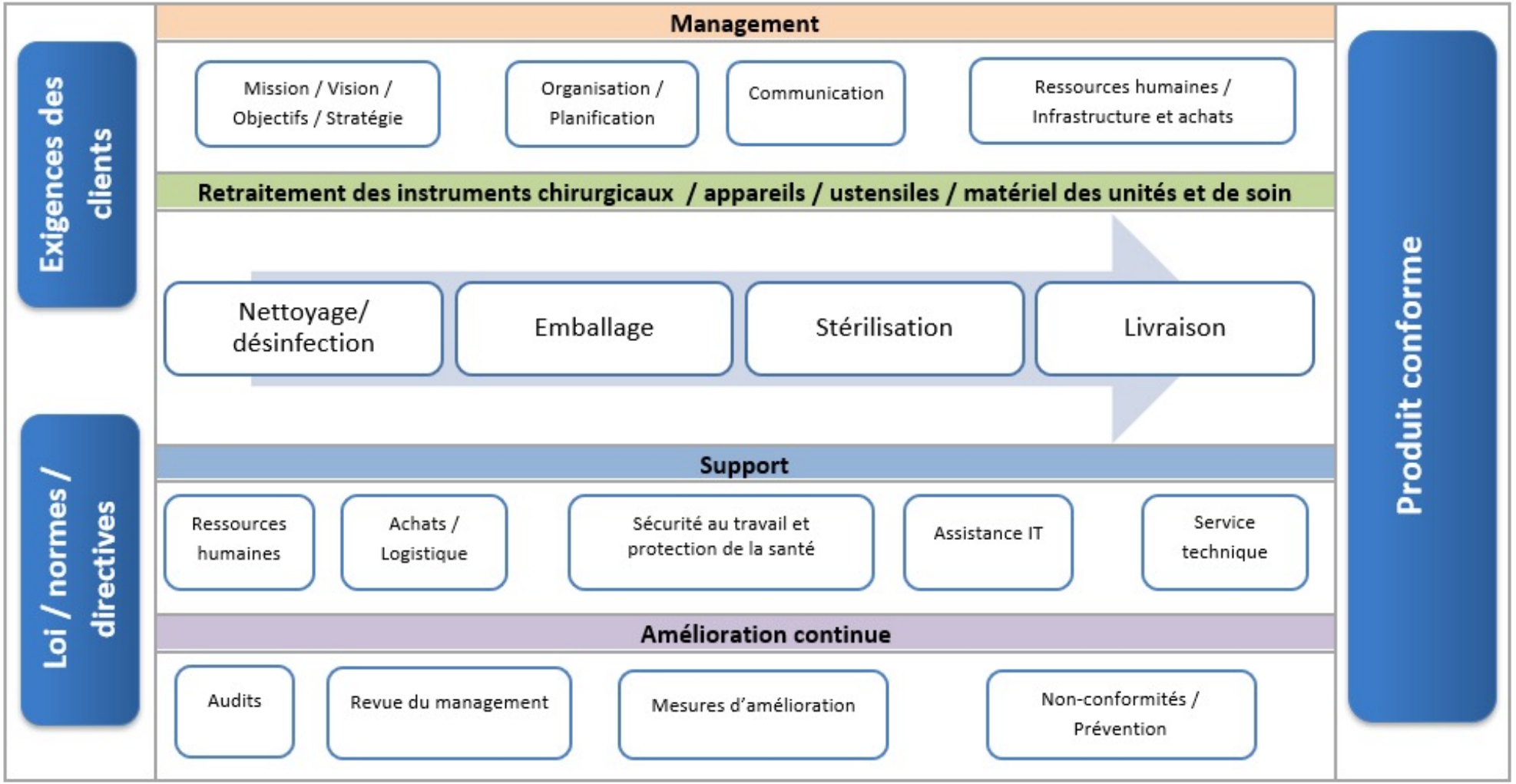
- 2nd version in December 2016
  - Adapted to the requirements of ISO 13485

- 3rd version **December 2021**
  - Ordinance on medical devices of 1 July 2020
  - Medical Device Regulation (Europe)
  - Other laws, ordinances and normative rules

The Swiss Good Reprocessing Practices for Medical Devices :

- Added value for QMS, device compliance
- Link to ISO 13485 requirements
- Added value for risk management, patient and employee safety

Swiss Good Reprocessing Practices for Medical Devices (BPR)



CONTENTS OF THE GOOD PRACTICES

Good Reprocessing Practices for Medical Devices	ISO 13485
1 Field of application 1.1 General information 1.2 Scope of application	1 Field of application
2 Main reference documents 2.1 Legal aspects 2.2 Competencies for inspections	2 Normative references
The field of application indicates which institutions are required to comply with these requirements. The BPRs set out in detail the legal framework for reprocessing.	

CONTENTS OF THE GOOD PRACTICES

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Good Reprocessing Practices for Medical Devices	ISO 13485
3 Quality management 3.1 General requirements 3.2 Definitions (according to EN 9000) 3.3 The PDCA (Plan-Do-Check-Act) cycle 3.4 Risk management 3.5 Risk classification table (Spaulding) 3.6 Documentation requirements	4 Quality management 4.1 General requirements 4.2 Documentation requirements

BPRs correspond to the ISO 13485 standard with regard to QMS requirements, including reprocessing processes.

The chapters on risk management are explained in detail and illustrated with examples.

CONTENTS OF THE GOOD PRACTICES

Good Reprocessing Practices for Medical Devices	ISO 13485
3.7 Traceability	7.5.8 Identification 7.5.9 Traceability 7.5.10 Property of the customer 7.5.11 Product Preservation
The BPRs set out requirements for traceability on the basis of the relevant Swiss laws and ordinances.	

BPRs go hand in hand with the requirements of the ODim and the MDR (EU): traceability of flexible endoscopes must be ensured individually all the way down to the patient.

CONTENTS OF THE GOOD PRACTICES

Good Reprocessing Practices for Medical Devices	ISO 13485
4 Roles and responsibilities 4.1 Management's responsibility 4.2 Listening to customers 4.3 Roles and responsabilities, authority and communication	5 Management's responsibility 5.1 Management's commitment 5.2 Customer orientation 5.3 Quality policy 5.4 Planning 5.5 Roles and responsabilities, authority and communication 5.6 Management review

The BPRs explain in a clear manner the main requirements of the reprocessing standard. These requirements are easy to implement.

The BPRs stress the need for good training (since 2018 TDM CFC).

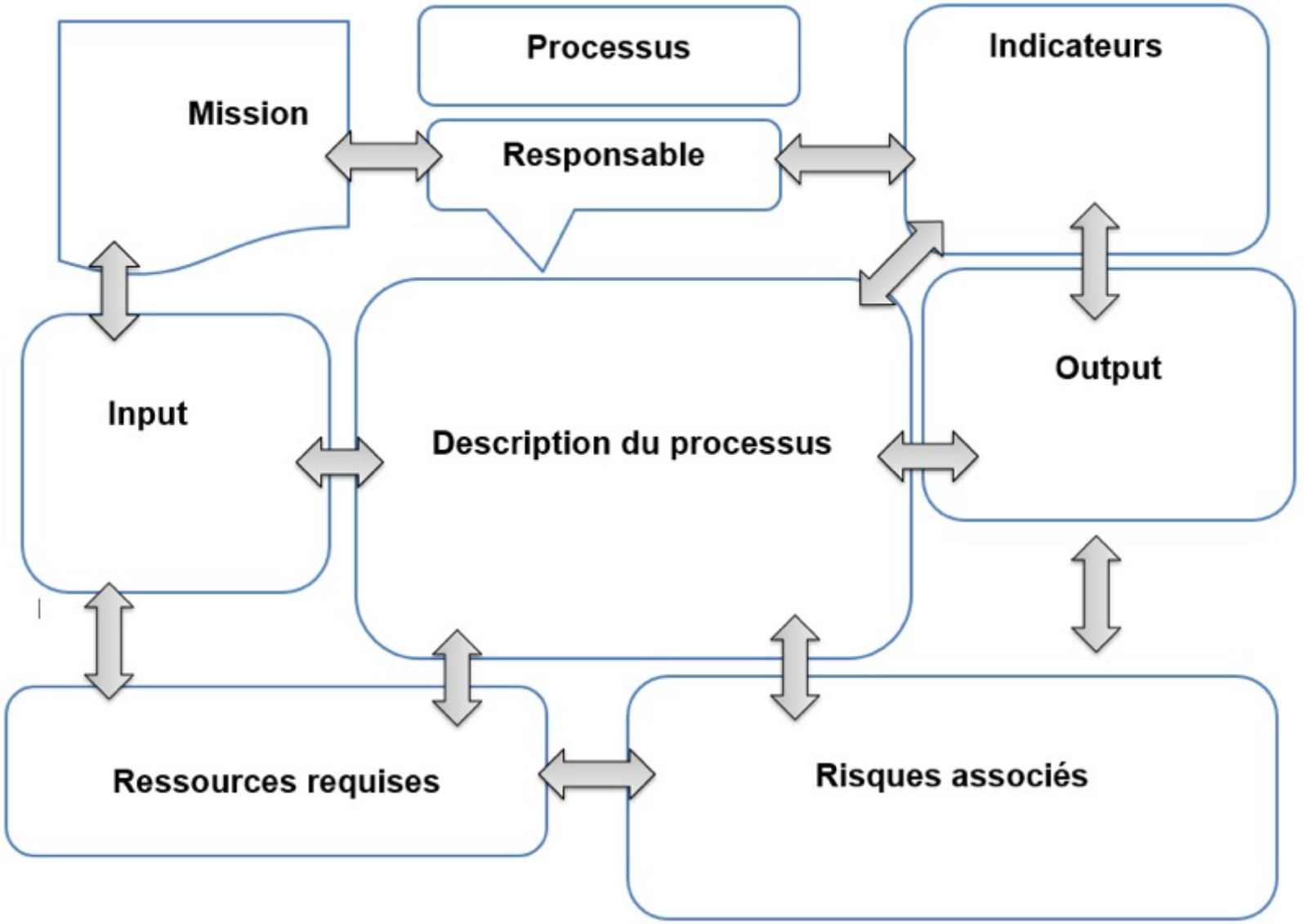
CONTENTS OF THE GOOD PRACTICES

Good Reprocessing Practices for Medical Devices	ISO 13485
5 Resources 5.1 Human resources 5.2 Premises 5.3 Ventilation and air quality 5.4 Compressed medical air 5.5 Water 5.6 Equipment 5.7 Support services	6 Resource management 6.1 Provision of resources 6.2 Human resources 6.3 Infrastructure 6.4 Work environment and contamination control
The BPRs explain in a simple and concrete manner how the requirements can be implemented in accordance with the state of the art.	

CONTENTS OF THE GOOD PRACTICES

Good Reprocessing Practices for Medical Devices	ISO 13485
6 Production 6.1 Planning production 6.2 Client-related processes 6.3 Design and development 6.4 Conformity of the products purchased	7 Production 7.1 Planning production 7.2 Client-related processes 7.3 Development 7.4 Purchasing
The BPRs lay down the essential principles in an analogous way to ISO 13485.	

CONTENTS OF THE GOOD PRACTICES



CONTENTS OF THE GOOD PRACTICES

Good Reprocessing Practices for Medical Devices	ISO 13485
7 Reprocessing of medical devices 7.1 General information 7.2 Special circumstances 7.3 Pre-disinfection 7.4 Cleaning and disinfection 7.5 Cleanliness and functionality check 7.6 Packaging 7.7 Sterilization 7.8 Storage 7.9 Expiry date of sterilized medical devices	7.5 Production and service provision 7.6 Control of monitoring and measuring instruments

The BPRs set out the processes required to provide a compliant medical device and service.

CONTENTS OF THE GOOD PRACTICES

Good Reprocessing Practices for Medical Devices	ISO 13485
8 Control of monitoring and measurement devices 8.1 Monitoring and measurement 8.2 Improvement actions 8.3 Control of nonconformities	8 Measurement, analysis and improvement 8.1 General information 8.2 Monitoring and measurement 8.3 Control of nonconformities 8.4 Data analysis 8.5 Improvement
BPRs comply with ISO 13485. No business can survive in the long term without continuous improvement measures. Customer feedback is essential.	

CONTENTS OF THE GOOD PRACTICES

Good Reprocessing Practices for Medical Devices	ISO 13485
9 Reprocessing for third parties 10 Surgical instruments on loan	7.5 Production and service provision
Special cases of reprocessing are dealt with in separate chapters of the BPR.	

SUMMARY

- BPRs are intended to help understand and implement the requirements of ISO 13485.
- The BPRs provide solutions for implementing laws, ordinances, standards and directives.
- BPRs can be applied in small or large reprocessing services.

SUMMARY

- The BPRs define the criteria for inspections (Swissmedic), audits (certification) and management's responsibility.

Text in red: requirement
Texts in blue: recommendation
Plain text: guidance, explanation

SUMMARY

Une qualification des performances des stérilisateurs doit être effectuée annuellement ainsi qu'après chaque modification importante (SN EN ISO 17665).

Pour des dispositifs médicaux semi-critiques (et critiques) qui ne peuvent pas être stérilisés : une valeur A_0 de 3000 est recommandée (50 min à 80°C, 5 min à 90° C, 1 min 25 sec à 95° C).

RISK MANAGEMENT

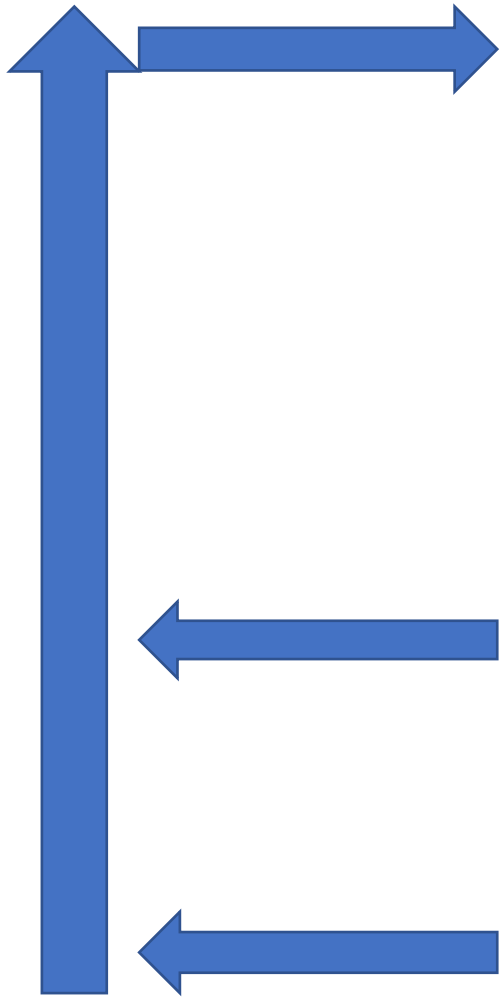
Risk management is a requirement under the European MDR and ISO 13485.

Risk management is a requirement under the BPRs.

The BPRs address the analysis and control of risks.

The BPRs risk management process is based on the provisions of ISO 14971.

BPR RISK MANAGEMENT PROCESS



Risk analysis

Identify risks; potentially dangerous situations.

Risk assessment

Assess the risks. How dangerous is the situation?

Risk management

Measures to reduce risks. Assess residual risks.

Efficiency monitoring

Regularly monitor and record measures to reduce risks.

Level of severity resulting from the hazard

Level	Criticality	Definition
1	low	No impact on the functioning of the MD
2	average	Interference with the functioning of the MD without risk to patient safety
3	serious	Impairment of the functioning of the MD with a risk to patient safety

Frequency is the probability of the risk occurring

Level	Frequency
1	Less than 1 x per year
2	At least 1 x per year
3	1-5 x per quarter
4	Several times a month
5	Several times a week

Probability of detection

Level	Definition	Examples of criteria
1	Easy to detect	Visible to the naked eye
2	Requires a simple check	Using a magnifying glass
3	Requires special equipment	Apparatus for detecting leakage in sheathed instruments
4	Not detectable	Invisible/non-measurable: dosing system without error message/non-sterile product

A link is established between the level of severity and the frequency of occurrence:

Frequency H Gravity S	1	2	3	4	5
1	1	2	3	4	5
2	2	4	6	8	10
3	3	6	9	12	15

Next, we consider the probability of detection:

S x H / Entdeckungswahrscheinlichkeit	1	2	3	4
1	1	2	3	4
2	2	4	6	8
3	3	6	9	12
4	4	8	12	16
5	5	10	15	20
6	6	12	18	24
8	8	16	24	32
9	9	18	27	36
10	10	20	30	40
12	12	24	36	48
15	15	30	45	60

BPR RISK MANAGEMENT

Criticality from 1 to 10: acceptable risk; minor corrections possible, redress the situation within two weeks max.

Criticality from 12 to 27: reduce risk, corrective action required, redress situation within a week max.

Criticality from 30 to 60: reduce risk, extensive corrections required, address situation within 48 hours.

EXAMPLE: BPR RISK ANALYSIS

Evénement	Identification de la situation critique		Estimation et évaluation des risques associés							Maîtrise des risques				Contrôle de l'efficacité des mesures prises					
	Etape du processus de retraitement	Description de la situation	Causes potentielles	Conséquences	Contrôles existants, efficacité	Gravité	Fréquence	Détectabilité	Criticité	Propriétaire du risque, Qui?	Réduire ou Accepter?	Plans d'action	Délais	Gravité	Fréquence	Détectabilité	Criticité	Réduire ou Accepter?
DM souillé après lavage	Lavage	DM visuellement souillé après LD	Zone d'ombres lors du chargement du LD	Perte de temps	Procédure de préparation de la charge	1	3	1	3	Agent de stérilisation	Réduire	Contrôle des paramètres du LD	Immédiat	1	2	1	2	Accepter
			Panier de lavage trop rempli	Autres DMx potentiellement souillés	Contrôles de propreté des DMx							Formation du personnel	1 semaine					
			Défaut du cycle de lavage	Autres cycles non conformes	Paramètres de libération de la charge													
DM souillé avant utilisation au bloc	Conditionnement	DM visuellement souillé au bloc	Défaut de contrôle au conditionnement	Recherche d'autre DM identique au bloc	Contrôle de propreté des DMx	3	2	4	24	Responsable stérilisation	Réduire	Formation du personnel	1 semaine	1	1	2	2	Accepter
				Retard d'intervention	Inventaire des DMx stériles							Absence de DM unique	6 mois					
				Report d'intervention								Double contrôle sur DM unique	1 mois					
Panne alimentation vapeur centralisée	Sterilisation	Plus de vapeur disponible	Panne technique sur réseau	Arrêt des stérilisateurs	Surveillance du réseau d'alimentation	2	1	3	6	service technique	Réduire	Doubler alimentation	1 an	1	1	1	1	Accepter
			Panne ciblée sur un stérilisateur	Retard dans prise en charge des DMX	Générateur de vapeur de secours							Installer générateur indépendant	1 à 3 ans					
			Maintenance technique sans avertir	Report d'activités opératoires								Communication lors de maintenance	Immédiat					
DM non stérile livré au client	Stérilisation	DM n'a pas été stérilisé et livré	Marche en avant non respectée	Infections potentielles	Procédure de libération de la charge	3	2	2	12	responsable stérilisation	Réduire	Formation du personnel	1 semaine	1	1	2	2	Accepter
		Défaut de cycle de stérilisation	Libération de la charge non conforme	Autres DMx potentiellement concernés	Contrôles de l'utilisateur final							Double visa sur dossier de stérilisation	Immédiat					
				Rappel de la totalité de la charge	Graphiques de référence							Formation-sensibilisation des clients	6 mois					
				Image du service vis-à-vis des clients														

CONCLUSION

BPRs are for everyone: small and large reprocessing services; certified and non-certified.

BPRs provide direction, homogeneity of reprocessing. They refer to related guidelines (Swissmedic).

BPRs allow for product compliance (safety for patients and users).

BPRs are a tool to help implement the European MDR and the ODim.

Thank you


RAHMET
GRAZIE
OBRIGADO
谢谢
HVALA
THANK YOU
KIITOS
TAK
SHUKRAAN
MERCI
DANK JE
BARKA
DANKE
GRACIAS
ευχαριστώ
СПАСИБО
TACK
TAKK
ARIGATO