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Société Suisse de Stérilisation Hospitalière  
Società Svizzera di Sterilizzazione Ospedaliera

# ***Swiss guide for the transport of contaminated or sterile reusable Medical Devices for CSSDs***

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## ○Endorsed by the following organizations



Swissmedic, Institut suisse des produits  
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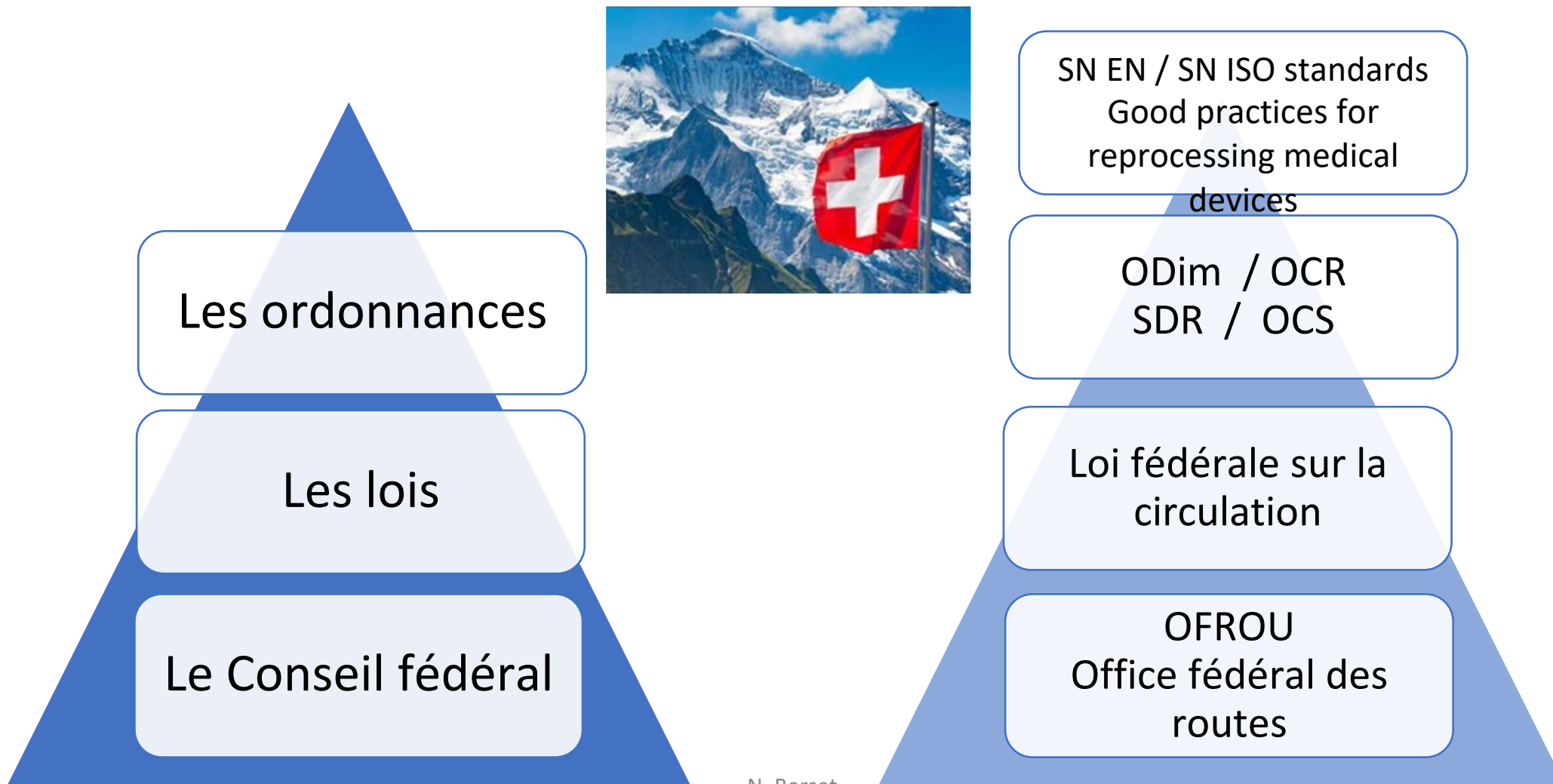
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SSSH  
<http://www.sssh.ch/>



Société suisse d'hygiène hospitalière  
SSH  
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- **Why a guide on transport?**
  - All CSSDs are concerned
  - Transport is part of the reprocessing process
  - Outsourcing of reprocessing on the rise
  - No official document on this issue in Switzerland
  - 2021 BPR update



- **ODim: Ordinance on Medical Devices (May (26 2021))**
  - Art. 4 Other definitions, letter e: reprocessing : the process by which a used medical device is reprocessed to allow safe reuse, including cleaning, disinfection, sterilization, and related procedures such as packaging, **transport** and storage [....]
- **OCR: Ordinance on Road Traffic Rules**
  - Driving ban on certain days (Sundays, public holidays corresponding to the cantons)
  - Between 10pm and 5am, **driving ban for heavy vehicles**
- **SDR: Decree on the transport of dangerous goods**
  - On the transport of dangerous goods
- **OCS: On safety advisers for the transport of goods by road, rail or inland waterway**
  - On the training and skills of persons in charge of the transport of dangerous goods



- **SN EN ISO 17664-1:** Processing of healthcare products - Information on the reprocessing of medical devices to be provided by the manufacturer
- Avoid damaging the MD during transport, the use of specific trolleys, containers, lids and other accessories may be recommended by the manufacturer of the MD

- **ADR:** European legislation
  - On packaging requirements
  - The packaging must be identified and bear the mention:

**Used health care products**

or

**Used medical equipment**

- No need to affix information on the vehicle, only on the cabinets and transport boxes

- Marking resistant to washing (mechanical or manual) or single use
- Closure system that secures the integrity of the contents
- Recognizable closure system between soiled and sterile MDs
- Delivery note

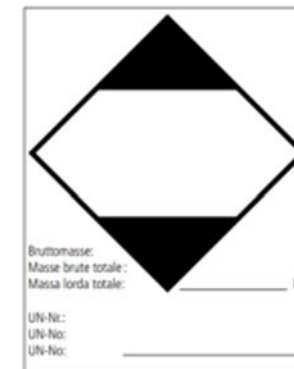


- **Dangerous goods**
  - Substances that may threaten human and wildlife health and harm the environment
- Examples:
  - **Infectious material**: material known or suspected to contain pathogens
  - Corrosive material
  - Flammable material
  - Toxic material
  - And more.....

- **Transport process**
  - Moving reusable MDs from the site of use to the reprocessing site and back
- **Internal transport**
  - Pathways through the facility
- **External transport**
  - Public roads, outside the facility

- The path with the least risk will be preferred
- A written contract must define the roles and responsibilities of each party
- The MDs should be insured according to the average value transported
  - List of all MD ownership scenarios (customer owned, loans)
  - Insurance for business interruption or damage?
- Emergency transport: written procedure with the same requirements

- Mailing possible under certain conditions
  - (LQ Limited quantities)
- Maximum 30 kg
- The sum of the edges (length/width/height) must not exceed 2 metres
- Beware of the many different postal rates!



Label for transport by post

- Knowledge and skills related to transportation processes
  - Downgraded mode in case of interrupted, blocked or delayed delivery
  - List of contact persons + phone number
- Initial and further training for each driver (1x year for example)
- Occupational health and safety principles for the transport of dangerous goods
- Ergonomics for loading
- Avoid transshipment and favour direct transport

- Ensure that the MDs are protected from atmospheric conditions during transport
- Rigid roof and walls
- The floor must be smooth and have a drainage system
- Resistance to surface disinfectants
- Fixing system to immobilize cabinets or boxes during transport



- The transport cabinets and bins used must protect the integrity of the medical devices during transport



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- Constraints:
  - mechanical, temperature change, humidity and dust levels
- Dew point
- Temperature
- Humidity
- Changes in pressure
  - Difference in altitude between start and end points
- Mechanical constraints
  - State of roads and paths
  - Prevention: silicone supports to keep the MDs inside the cases
- Dust

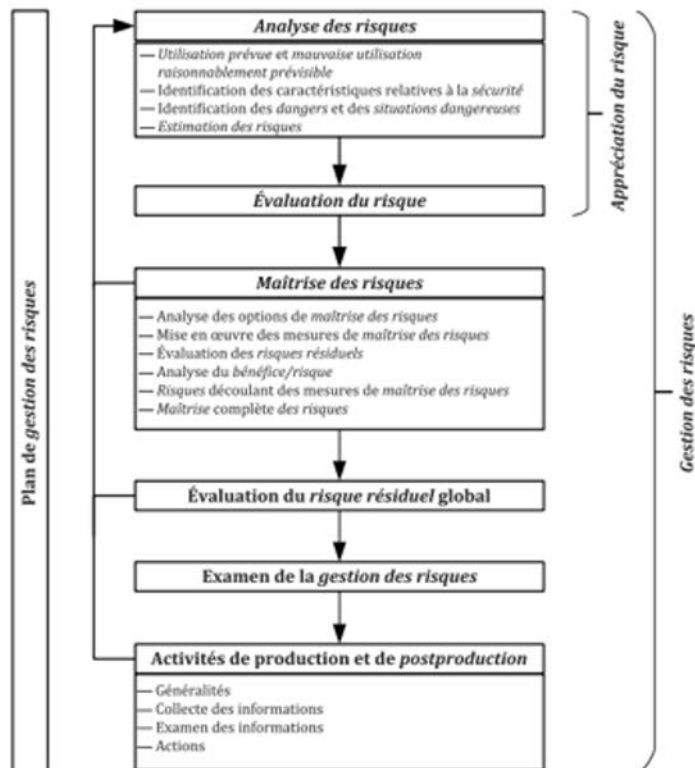
Dew points as a function of humidity and temperature

Temperature	Humidity	Dew point	Humidity	Dew point
18°C	30%	0.2°C	60%	10.1°C
25°C	30%	6.2°C	60%	16,7°C
30°C	30%	10.5°C	60%	21.4°C
40°C	30%	19.1°C	60%	30.7°C

- Vehicles
  - Protocol drafted and approved by the hygiene service
  - The driver (s) or dedicated staff must be trained
  - QMS: Follow-up sheet with signatures
- Cabinets, transport boxes
  - Must be cleaned at each trip to CSSD
- The premises
  - A cleaning and disinfection plan must be drawn up and approved by the hygiene department

- Cabinet maintenance plan
  - For transport cabinets
    - Wheel and door checks.....
    - Assess the need for spare wheel stock
    - Sufficient number of cabinets
  - Make sure that the wheels and their fastening system are made of stainless steel

- CSSD must ensure regular supply of medical devices
- Risk analysis according to SN EN ISO 14971



Example of risks: geographical features

- Landslide
- Earthquake
- Snowfall
- Floods
- Storm

Example of internal risk :

- Elevator out of order

Figure 1 — Représentation schématique du processus de gestion des risques


- Set-up qualification
  - Suitability of vehicles and cabinets, boxes
  - Adequacy of loading/unloading areas
  - Transport path and alternative paths
  - Signed contracts, insurance
  - Staff training



- Operational qualification
  - Test the components under the most critical situations
  - Maximum vehicle load (traffic permit!)
  - Maximum load of transport cabinets
  - Timetable, duration
  - Compatible with the customer's organization

- Performance qualification
  - Verification of the entire transport circuit with the usual MDs
  - An observer monitors the circuit once a year
  - The results are documented and entered into the QMS
  - In case of a major change, performance qualification is redone

- The transport of medical devices can lead to potential hazards critical to patient care
- It is important to carry out a risk assessment before transport
- Take all necessary measures according to the state of the art
- Patient care depends on safe transport of MDs



Thank you for your attention