







17 / 20 NOVEMBER 2021 CICG, GENEVA, SWITZERLAND

Sterile processing technologist federal diploma, a new profession in Switzerland

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SGSV/SSSH/SSSO



History

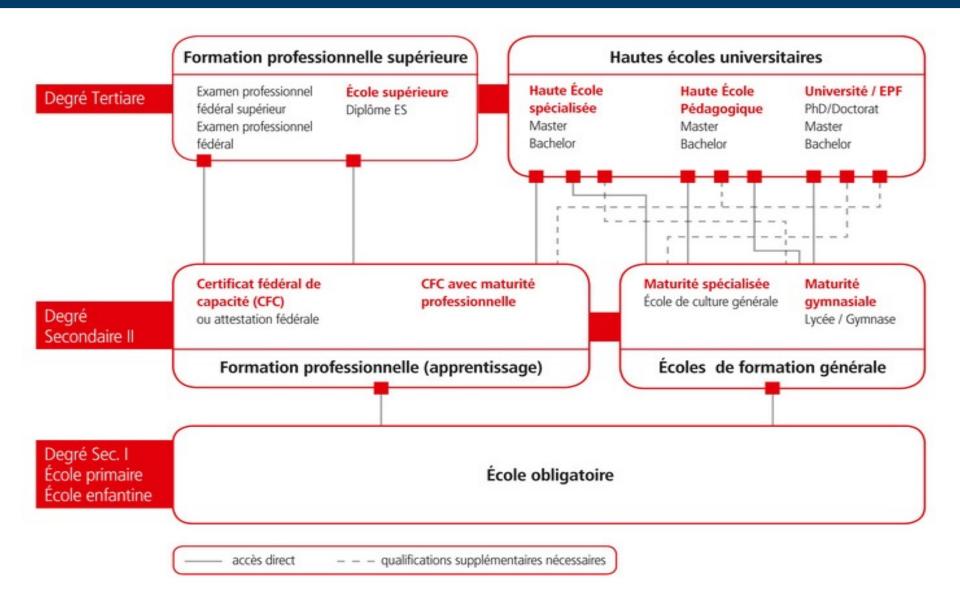


- 2007: Decision of the General Assembly of the SSSH to take steps to develop a new profession in Switzerland
- 2008: EFHSS Congress in Milan
 - Presentation of the new training project in Switzerland
 - The conclusions:
 - It is becoming necessary to create a new profession with a federal certificate of competence
 - There is still a long way to go, because there are still several points to clarify.
 - What has happened since?



Swiss education system





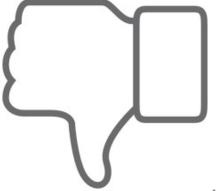


Practices in Switzerland



2007 - 2008 Survey on reprocessing practices for medical devices at the request of the Swiss authorities

- Objectives
- State of the art of sterilization in Switzerland to determine future developments
- Basis of discussion for negotiating with the authorities
- Presentation in 2009 at the Swiss Congress
- Mostly technical information
- Two categories of sterilization
 - Universities: 40 FTE
 - Other: 6 FTE





Collaboration with a company



2009 - 2010: Collaboration with a specialized company

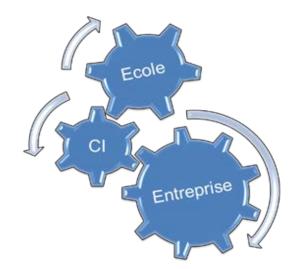
(Graf und Partner)

to create a new profession

of the file to obtain the first green light from the authorities What type of training?

- Competency-based dual training





Company: 4 days a week

School: 1 day a week

CI: 13 days over the 3 years





Membership in ODASanté



2010 :

SGSV/SSSH/SSSO joins ODASanté

OdASanté

Cost: 15'000,- CHF per year

Contributions: health care professionals with extensive

experience in other professions



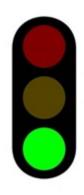
Needs analysis



2011 - 2012 :

Needs analysis for the new profession and second green light from the authorities

Survey of hospital management



Visit to a sterilization facility with representatives of other professions who needed to be convinced

Comment from a participant:

Why would we need a new profession? It is a simple process: wash, pack and sterilize. There is no need for a new profession!!!



Reform Commission



2013 - 2016: A reform commission was created to develop training requirements, in particular:

- Curriculum
- Training plan
- Name of new occupation

Representatives:

- Swiss Confederation (SEFRI)
- Cantons (3 language regions)
- Employers (3 language regions)
- SSSH (3 language regions)





Name of the new profession and conditions



- Medical device technologist
 - Technologist = technology specialist
 - Technician could not be used:
 - Reserved for engineering schools
 - Not too long



- Profile
 - Interested in the techniques
 - Manual skills
 Precision and meticulousness
 - Sense of responsibility
 - Ability to handle stress

. Conditions

- Compulsory education completed

- Good results and good understanding - in natural and technical sciences

- No impaired color vision





Training plan

Domaines de compétences		Compétences opérationnelles		\Rightarrow		22	
		1	2	3	4	5	
А	Gestion des dispositifs médicaux et organisation des tâches inhérentes au processus de retraitement	des clients et déterminer	A2 Planifier et organiser les taches de manière autonome et efficace		A4 Assembler, emballer et transporter les commandes	A5 Soumettre des propositions d'amélioration des processus opérationnels	
В	Lavage et désinfection des dispositifs médicaux	B1 Préparer les appareils pour le lavage et la désinfection ; effectuer les tests de routine	B2 Trier et préparer les dispositifs médicaux en vue de leur lavage et de leur désinfection	B3 Préparer la charge ; effectuer un lavage et une désinfection mécaniques des dispositifs médicaux	B4 Effectuer un lavage et une désinfection manuels des dispositifs médicaux	B5 Effectuer les contrôles de processus et libérer la charge	
С	Assemblage et emballage des dispositifs médicaux	C1 Préparer les apparells de scellage et d'essal de fonctionnalité ; effectuer les tests de routine	C2 Contröler, entretenir et assembler les dispositifs médicaux	C3 Assembler, emballer et identifier les dispositifs médicaux en tenant compte des directives de sécurité et en optimisant l'utilisation des matériaux			
D	Stérillsation des dispositifs médicaux	D1 Préparer les apparells requis pour le processus de stérilisation à la vapeur saturée ; effectuer et documenter les tests	D2 Préparer les apparells requis pour le processus de stérilisation à basse température ; effectuer et documenter les essais de fonctionnailté	D3 Affecter les dispositifs médicaux à la méthode de stérilisation indiquée, préparer la charge de stérilisation conformément aux profils de charge validés et stériliser les dispositifs médicaux au moyen du procédé adéquat	D4 Réaliser les contrôles de processus et libérer la charge		
E	Assurance de la qualité et du respect des exigences établies par la législation et par des normes techniques	des appareils afin d'en	E2 Veiller à l'application des mesures et des directives de sécurité au travail et de protection de la santé	E3 Mettre en œuvre les mesures et les directives de protection de l'environnement	E4 Réaliser les tests périodiques sur les appareils	E5 Gérer les urgences et les situations de stress	





Example of operational competence (1)



- Area of competence B:
 - Washing and disinfection of MDs
- Competency B2
 - Sorting and preparing medical devices for washing and disinfection
- Examples of knowledge (15):
 - Explain the differences between thermostable and thermolabile medical devices, and between reprocessable and single-use devices
 - Explain the different devices and their areas of use, handling and cleaning
 - Use chemicals correctly in their field of work and assess the risks they present





Example of operational competence (2)



- Examples of skills / competences (10):
 - Respect hygiene standards
 - Assign medical devices to appropriate washing methods
 - Perform disassembly, assembly and functional checks of medical devices, as indicated
- Examples of soft skills (7):
 - Awareness of personal responsibility for the health of patients
 - Careful and thourough work ethics
 - Care in handling medical devices and equipment (awareness of risks)



- Curriculum (1)



- Ordinance of the SEFRI on the initial vocational training of medical device technologists with federal certificate of competence (CFC)
- 1. Purpose and duration: 3 years of training
- 2. Objectives and requirements: link with the training plan
 - 22 operational skills
- 3. Occupational safety, health protection and environmental protection
- Scope and location of training

Ordonnance du SEFRI sur la formation professionnelle initiale de technologue en dispositifs médicaux avec certificat fédéral de capacité (CFC)*

du 3 octobre 2017 (Etat le 1er janvier 2018)

87101

Technologue en dispositifs médicaux CFC Medizinproduktetechnologin EFZ / Medizinproduktetechnologe EFZ Tecnologa per dispositivi medici AFC / Tecnologo per dispositivi medici AFC

412.101.222.30



- Curriculum (2)



Enseignement	1re année	2º année	3e année	Total
 a. Connaissances professionnelles – Gestion des dispositifs médicaux et organisation des tâches inhérentes au processus de retraitement; lavage et 	80	60	60	200
 désinfection des dispositifs médicaux Assemblage et emballage des dispositifs 	80	60	40	180
 médicaux Stérilisation des dispositifs médicaux; assurance de la qualité et du respect des exigences établies par la législation et par des normes techniques 	40	80	100	220
Total Connaissances professionnelles	200	200	200	600
b. Culture générale	120	120	120	360
c. Éducation physique	40	40	40	120
Total des périodes d'enseignement	360	360	360	1080



- Curriculum (3)



1. Requirements for trainers

- MDR CFC + 2 years of experience
- Other CFCs + level 2 + 3 years of experience
- Degree from a university + at least 2 years of professional experience in the field of training they provide

2. Qualification procedure

- Prescribed practical work (4 hours)

40 % 20 %

- Professional knowledge
 - Written exam (3 x 50 min)
 - Oral exam: 30 minutes
- General knowledge

Experience notes (3 years of school)

20 %





Implementation



2017 - 2018 :







Implementation has been completed in the three language regions:

- Choice of training centres
 - Careum (Zurich), ESSanté (Lausanne), Centro Professionale Sociosanitario Medico-Tecnico (Lugano)
- Training manual
 - All relevant documents available
 - Who teaches what and where?
- Course materials written
- Training of trainers in companies
- Minimum requirements for training companies
- Teacher selection





Course materials



- About 700 pages
- 5 booklets + 2 supplements: glossary and standards















- Basic data, exercises, reflection, etc.
- Only digital first, then printed complement
- Publisher: Careum Verlag verlag@careum.ch
- Cost to SGSV/SSSH/SSSO: CHF 100000



Minimum requirements / training companies



- Infrastructure and equipment
 - Separate work areas:
 - · washing area, packaging area, sterile storage area
 - At least one washer disinfector compliant with SN EN ISO 15883
 - At least one welding machine
 - At least one steam sterilizer compliant with SN EN 285
- Other basic requirements
 - Be able to teach all operational skills
 - Reprocess equipment from at least one operating room with the following surgical areas:
 - General surgical instruments
 - Minimally invasive surgery
 - Orthopedics
 - Gynecology

Practical internships:

- 5 days in the operating room
- 2 days in the endoscopy department
- 2 days with another important customer





First year



2018 A first group of students started their training in each of the 3 linguistic regions

2018 - 2021 :

Adjustments were made to correct the imperfections detected and the qualification procedure was finalized with the writing of the oral and written exams.

 Working group to write the exams (practical, written and oral) for the whole of Switzerland in the 3 languages

2020:

Good practices Good practices for the management of MDR trainees (apprentices)





First CFC MDR



2021

30 apprentices obtain the CFC in MDR

- 17 in German-speaking Switzerland
- 10 in French-speaking Switzerland
- 3 in Ticino









Formation préparatoire

à la procédure de qualification du CFC de technologue en

dispositifs médicaux (TDM)

People currently employed



2021 Preparation of a training course for people who have been working in sterilization for at least 5 years

Requirements

- At least 3 years of full-time experience in the field of MDR
- Experience in the 22 operational skills
- At least B1 level in French
 - according to the standards of the European Framework of Reference for Languages
- Have passed the general knowledge exam
- Hold the STE 1 or STE 2 certificate









Future



- Making the training sustainable
- Convince reluctant institutions
- Integrate the MDR CFC into legal documents, Good Practices and various recommendations
- Update course materials
- Develop a medical device technologist certificate for executives





Conclusion



I would like to thank all the people who have invested themselves during these 14 years to develop this new profession

There is still a lot of work to be done, so let's get to it, dear colleagues!

When training meets the requirements of the job, skills serve progress

Mouctar Keita



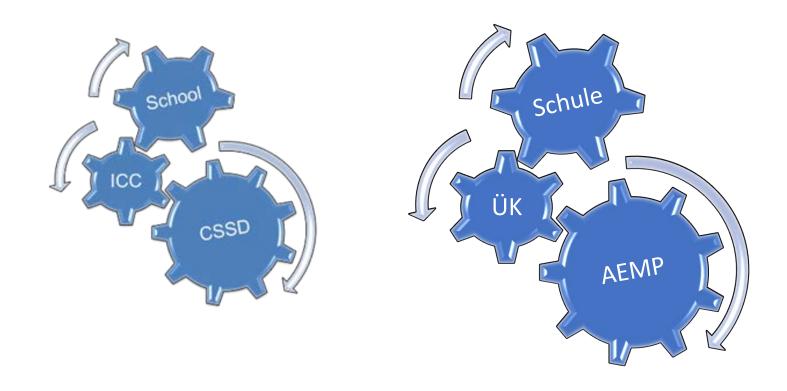




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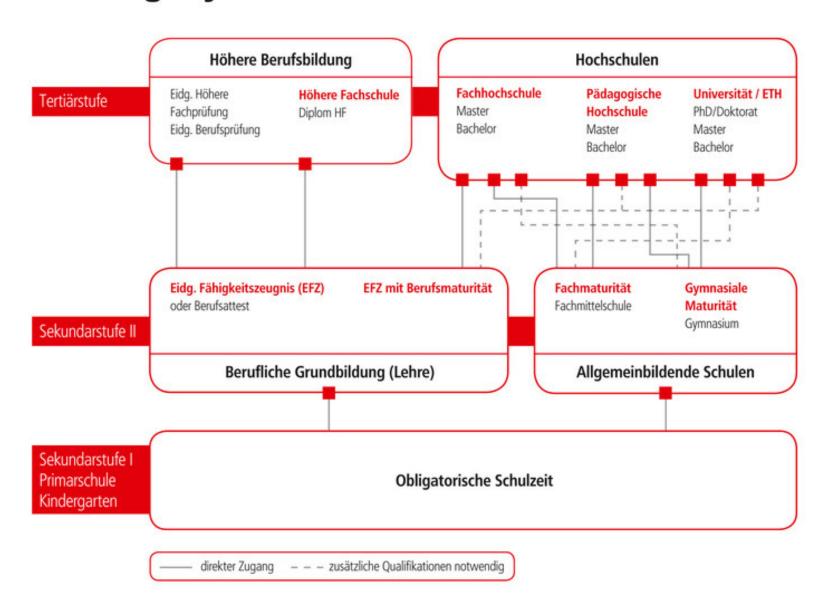
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Diagram for translators

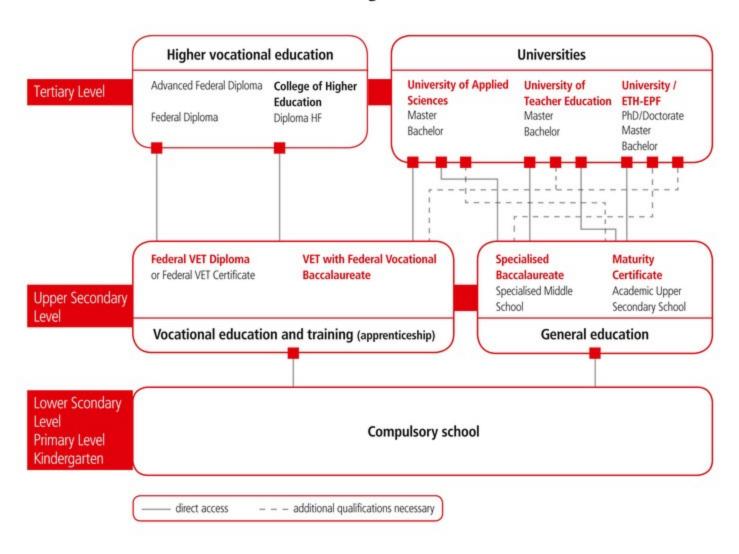


Į	Handlungskompetenzbereiche		Berufliche Handlungskom	petenzen	\Rightarrow			
•			1	2	3	4	5	
A	Bewirtschaften von Medizinprodukten und Organisieren der Arbeiten des Aufbereitungsprozesses		analysieren und	A2 Arbeiten selbstständig und effizient planen und organisieren	A3 Medizinprodukte und Verbrauchsgüter bewirtschaften	NAMES OF A PARTY OF THE PARTY O	A5 Vorschläge für Optimierungen der betriebli- chen Abläufe einbringen	
В	Reinigen und Desinfizieren von Medizinprodukten		und Desintektion	B2 Medizinprodukte für die Reinigung und Desinfektion triagieren und vorbereiten	B3 Charge zusammenstellen und Medizinprodukte maschinell reinigen und desinfizieren	B4 Medizinprodukte von Hand reinigen und desinfizieren	B5 Prozesskontrolle durchführen und die Charge freigeben	
С	Zusammenstellen und Verpacken von Medizinprodukten		Denetstellen Linci	C2 Medizinprodukte kontrollieren, pflegen und zusammensetzen	C3 Medizinprodukte unter Berücksichtigung von Sicherheitsvorschriften und Materialeffzienz zusammenstellen, verpacken und beschriften			
D	Sterillisieren von Medizinprodukten		Sterilisationsprozess mittels Sattdampf bereitstellen, Tests durchführen und		D3 Medizinprodukte der vorgegebenen Sterilisa- tionsmethode zuordnen, Sterilisationscharge gemäss den validierten Beladungsprofilen zusammenstellen und Medizinprodukte mit dem fachgerechten Prozess- verfahren sterilisieren	D4 Prozesskontrolle durchführen und die Charge freigeben		
E	Sicherstellen der Qualität und der Einhaltung der im Recht und in technischen Normen festgehaltenen Anforderungen		E1 Werterhaltung der Geräte durch Unterhalt sicherstellen	E2 Massnahmen und Vorschriften der Ar- beitssicherheit und des Gesundheitsschutzes sicherstellen	E3 Massnahmen und Vorschriften des Umweltschutzes umsetzen	E4 Periodische Tests der Geräte durchführen	E5 Notfälle und belastende Situationen bewältigen	

Bildungssystem der Schweiz



The Swiss education system



El sistema educativo en Suiza

