Results: BZAEK Survey on Testing Requirements for Sterilizers

Replies: 18

Replies provided by: Spain, Belgium (VVT), Cyprus, Greece, Switzerland, Germany, Latvia, Czech Republic, Netherlands, Austria, Malta, Finland, United Kingdom, Iceland, Croatia, Norway, Lithuania, Denmark

Background: At the regional level in Germany, regulatory provisions have been introduced that require pressure vessel testing for sterilizers (autoclaves) exceeding an operational age of 15 years. In practice, such testing often results in the device being deemed unusable. Only a limited number of units successfully pass the procedure, and the associated costs typically amount to €2,000 or more. At the same time, manufacturers and distributors frequently promote the replacement of existing devices with new equipment. To the best of BZAEK's knowledge, there have been no reported incidents involving sterilizers—such as explosions or comparable safety failures—that would justify the necessity of such stringent measures.

Based on discussions with manufacturers, these requirements are often said to be linked to broader European legislation on pressure equipment. BZAEK has reason to question this interpretation. At EU level, sterilizers fall within the scope of Directive 2014/68/EU (Pressure Equipment Directive, PED) , which sets harmonized requirements for design, manufacture, and conformity assessment prior to market placement, including essential safety requirements and final inspections. However, the PED does not regulate the operation of equipment throughout its lifecycle. It neither prescribes fixed inspection intervals nor establishes age-based thresholds or automatic decommissioning requirements. Instead, it leaves in-service inspection, maintenance, and operational safety largely to the competence of the Member States. Against this background, BZAEK would greatly appreciate insights on how this issue is addressed in other countries. The feedback gathered would be extremely valuable for its work and would help gain important insights from all over Europe.

Question: Are comparable testing requirements for older sterilizers in place?

Respondent	Reply	Additional comments:
Spain	**No**	In Spain, dental clinics are required to use Class B autoclaves due to the contact of instruments with blood and mucous membranes. The regulations do not differentiate based on the age of the autoclave but rather establish a series of periodic inspections for all of them.
Belgium	**No**	
Cyprus	**No**	

Council of European Dentists
President Dr. Freddie Sloth-Lisbjerg
Transparency register: 4885579968-84
Numéro d'entreprise: 0480.222.749
Avenue de Cortenbergh 89/6
B-1000 Brussels
T +32 (0)2 736 34 29
ced@cedentists.eu
www.cedentists.eu

Greece	**Yes**	Chemical indicators by means of specific paper stripes with thermoactivated ink are used for Type N autoclaves and for the limited number of Dry heat sterlizators still performing.
Switzerland	**No**	
Germany	**Yes**	Betriebssicherheitsverordnung (BetrSichV)
Latvia	**No**	
Czech Republic	**No**	
Netherlands	**Yes**	Section 8.8 of the Infection Prevention Guideline states that a NEN-, ISO- and CE-compliant steam sterilizer (NEN-EN 13060) should be used, provided that it is suitable for the instruments and materials being sterilized. Legal basis:The guideline is based on the Dutch Healthcare Quality, Complaints and Disputes Act (Wkkgz), which requires healthcare providers to deliver good quality care. The guideline provides a practical interpretation of this obligation and is used by the Dutch Health and Youth Care Inspectorate (IGJ) as a benchmark during inspections of dental practices.(applicable for ALL sterilizers).
Austria	**No**	
Malta	**No**	
Finland	**No**	
United Kingdom	**Do not know**	
Iceland	**Yes**	There is no separate legal requirement for older sterilizers in Iceland. The same laws and infection-control requirements apply regardless of the age of the equipment. The key requirement is that the sterilizer is properly maintained, tested, and able to demonstrate effective sterilization performance.
Croatia	**No**	
Norway	**No**	
Lithuania	**No**	
Denmark	**Open answer only =>**	In Denmark, sterilizers (autoclaves) are subject to the general national regulations governing pressure equipment and occupational safety. The regulatory framework is based on the EU Pressure Equipment Directive (PED 2014/68/EU) with regard to the design, manufacture, and placing on the market of pressure equipment, while in-service inspections are governed by national regulations administered by the Danish Working Environment Authority.

CED COUNCIL OF EUROPEAN DENTISTS

Question: Do specific age thresholds apply (e.g. 15 years, 20 years, etc.)?

Respondent	Reply	Additional comments:
Spain	**No**	
Belgium	**No**	
Cyprus	**No**	
Greece	**No**	All dentists graduated after 1995 purchace and use type S or Type B sterilizators (autoclaves) and they evaluate their performance either with mechanical indices (Printouts from the device) or with Chemical indicators outside or inside the pouches , or inside the stelization chamber.
Switzerland	**No**	
Germany	**Yes**	An inspection must be carried out no later than 10 years after the equipment is put into service. If the manufacturer guarantees safe operation, this period may be extended to 15 years.
Latvia	**No**	
Czech Republic	**No**	
Netherlands	**No**	
Austria	**No**	
Malta	**Do not know**	Only vacuum Autoclaves allowed.
Finland	**No**	
United Kingdom	**Do not know**	Perhaps equipment manufacturers may issue recommendations, but we are not specifically aware of such.
Iceland	**No**	The applicable requirements are based on performance, maintenance, validation, and documented effectiveness rather than the age of the equipment. An older sterilizer may remain in use provided it can be properly maintained, tested, and shown to achieve the required sterilization standards.
Croatia	**No**	
Norway	**No**	
Lithuania	**No**	
Denmark	**No**	Periodic inspections may be required depending on the classification of the pressure equipment. However, there are no specific age-based requirements applicable to sterilizers. We are not aware of any requirement under Danish legislation

Council of European Dentists
President Dr. Freddie Sloth-Lisbjerg
Transparency register: 4885579968-84
Numéro d'entreprise: 0480.222.749
Avenue de Cortenbergh 89/6
B-1000 Brussels
T +32 (0)2 736 34 29
ced@cedentists.eu
www.cedentists.eu

		for mandatory pressure equipment inspections solely because a sterilizer has been in operation for 15 years, nor is there any requirement for automatic decommissioning based on age.

Question: How are these requirements implemented in practice?

Respondent	Reply:
Spain	The controls required periodically are: a) Physical controls: time, temperature, and pressure. A record must be kept of each sterilization cycle. b) Chemical controls: colorimetric change, recorded for each cycle. c) Biological controls: using spore tests, mandatory once a week (for dental clinics with a high volume of patients) or once a month (for clinics with a low volume of patients). All these controls must be recorded in a logbook or a traceability system. In addition, autoclave validation is required at the time of installation and annual validation, performed by an authorized technical service.
Belgium	Everyone is responsible for the proper functioning, but there is no deadline.
Cyprus	All the required tests are performed by the technical support staff at the service but the service is not mandatory by law.
Greece	These requirements are implemented thanks to the Continuous Education system,the performance of the dentists and the dental assistants responsible for IC issues and through concise publications/quidelines from the Universities and the National Organization of Public Health (EODY in Greek or NOPH).
Switzerland	/
Germany	Customer services remind operators of this obligation. However, due to the high cost of pressure testing, they recommend purchasing a new steriliser. The regulatory authorities can check compliance with legal requirements and impose fines in the event of non-compliance.
Latvia	mandatory check ups for 1. functional workflow 2. electro safety 3. technical service acc. regulation.
Czech Republic	/
Netherlands	Current guideline Infection Prevention: - Use a steam sterilizer in accordance with the manufacturer's instructions. - Operate and document the sterilization process in compliance with NEN-EN 13060. - Carry out and document routine user maintenance in accordance with the manufacturer's instructions. - Ensure that periodic maintenance and performance testing are performed and documented in accordance with NEN R8153 by - the supplier or another service provider authorized by the manufacturer.
Austria	/
Malta	A yearly check with a health inspector who checks that a service was carried out and appropriate tests done.

Finland	/
United Kingdom	/
Iceland	Does not apply.
Croatia	We do not have any requirements implemented in practice.
Norway	/
Lithuania	In accordance with current legislation and infection control requirements, only Class B autoclaves may be used in Lithuanian dental facilities. Currently, the main focus is on ensuring that autoclaves comply with harmonised European standards (e.g., EN 13060 for small steam sterilisers, EN 285 for large sterilisers), which define pressure, temperature, and safety parameters.
Denmark	To ensure that a sterilizer continues to meet the requirements for effective sterilization, ongoing monitoring of the sterilization process is carried out in accordance with relevant national infection prevention and control guidelines. This includes regular biological, chemical, and physical monitoring at specified intervals to verify that the sterilization process is functioning correctly and continues to provide the required level of patient safety. The continued use of a sterilizer therefore depends both on compliance with applicable inspection and maintenance requirements and on documented quality assurance demonstrating that the equipment continues to operate safely and effectively.

Question: Is this issue widely known and discussed among dental practitioners in your country?

Respondent	Reply	Additional comments:
Spain	**Yes**	Dental associations provide written information on the main national and regional regulations when a dentist registers. This information includes, among other things, details regarding X-ray procedures, environmental protection, disposal of biological waste, sterilization, and the mandatory first-aid kit for medical emergencies.
Belgium	**No**	
Cyprus	**No**	
Greece	**Yes**	It is well known and extensively pesented on many scientific presentations such as Conventions, Symposiums and Continuous Education Sessions providing them additional Cont.Educ.Points . It is also extensively tought to the Undergraduate and Postgraduate level students through the relevant studies' programmes.

Switzerland	**No**	
Germany	**Yes**	Dentists criticise the mandatory pressure test as an unreasonable and costly bureaucratic requirement.
Latvia	**No**	
Czech Republic	**No**	
Netherlands	**Yes**	I also reviewed the draft versions of the new guideline. In the future, we will refer to the Dutch National Guideline on Cleaning, Disinfection and Sterilization of Reusable Medical Devices (SRI Guideline): https://richtlijnendatabase.nl/richtlijn/reiniging_desinfectie_en_sterilisatie_herbruikbare_medische_hulpmiddelen/randvoorwaarden_sterilisatie.html This guideline states: "To ensure the reliability of the sterilization process, the sterilizer must undergo periodic maintenance in accordance with the manufacturer's instructions. This includes, among other things, the calibration of temperature and pressure sensors." Based on my reading, the guideline does not prescribe a maximum service life for sterilizers, nor does it require mandatory replacement after a specified number of years.
Austria	**No**	
Malta	**Yes**	
Finland	**No**	
United Kingdom	**No**	We would have taken questions on this aspect if it were the case, I'm not aware of our team being asked such questions from our member dentists.
Iceland	**No**	
Croatia	**No**	
Norway	**Do not know**	
Lithuania	**No**	Discussions regarding technical and other requirements take place every 5 or more years, when infection control documents and regulations are reviewed at the national level.

Question: Are you aware of reported incidents involving sterilizers—such as explosions or comparable safety failures – at your national level?

Respondent	Reply	Additional comments:
Spain	**No**	

Belgium	**No**	
Cyprus	**No**	
Greece	**No**	Many years ago (more than 20) an accident occurred due to an attempt of the dentist to violate the regulations concerning the early opening of the autoclave (type N) door long after the minimization of the steam pressure inside the chamber.
Switzerland	**No**	
Germany	**No**	
Latvia	**Do not know**	
Czech Republic	**No**	They are OK , just producers are trying to stop them to make more business with new devices.
Netherlands	**No**	
Austria	**No**	
Malta	**No**	
Finland	**No**	
United Kingdom	**No**	
Iceland	**No**	
Croatia	**No**	
Norway	**No**	
Lithuania	**No**	Lithuania has a national system for reporting incidents related to technical nonconformities. Information is analysed. It is mandatory to report any technical nonconformities and to ensure that additional inspections are conducted after the defects have been corrected.

Any additional comments/information that you wish to provide:

Respondent	Additional comments:
Switzerland	Der Druckbehälter eines zahnärztlichen Autoklaven stellt bei sachgemässem Betrieb kein relevantes Sicherheitsrisiko dar, da moderne Geräte nach hohen technischen und regulatorischen Sicherheitsstandards konstruiert werden und mit vergleichsweise

	niedrigen Betriebsdrücken von rund 2 bar arbeiten. Zudem hängt das Gefährdungspotenzial eines Druckbehälters nicht nur vom Druck, sondern wesentlich auch vom Volumen ab, welches bei Praxisautoklaven mit typischerweise 17 bis 30 Litern sehr gering ist im Vergleich zu Druckbehältern, wie sie in Gewerbe und Industrie verwendet werden. Im Rahmen der regelmässigen Wartung gemäss Herstellervorgaben, üblicherweise jährlich oder in den vom Hersteller festgelegten Intervallen, werden sämtliche relevanten Komponenten wie Sensoren, Sicherheitsventile, Dichtungen und die Dichtigkeit des Systems überprüft, wodurch ein sicherer Betrieb gewährleistet wird. Im Rahmen dieser Gerätewartung wird der Druckbehälter optisch und funktionell geprüft, weitergehende vertiefte Prüfungen des Druckbehälters werden nicht gemacht und sind auch Hersteller-seitig nicht empfohlen. Die verfügbare Literatur zu Autoklavenzwischenfällen in zahnärztlichen und medizinischen Einrichtungen beschränkt sich auf Sterilisationsversagen und mikrobiologische Kontamination, nicht auf mechanische Druckbehälterversagen oder Explosionen. Es gibt keine identifizierten Studien über schwerwiegende Zwischenfälle mit dem Druckbehälter selbst (wie Explosionen, Bersten oder strukturelle Versagen). Die fehlende Evidenz zu Druckbehälterproblemen deutet darauf hin, dass solche Zwischenfälle extrem selten sind, vermutlich aufgrund strenger technischer Sicherheitsstandards und regelmässiger Wartungsanforderungen. Soviel etwas ausführlicher zu dieser Thematik aus Schweizer Sicht. ***Auto translation**: When operated correctly, the pressure vessel of a dental autoclave poses no significant safety risk, as modern units are designed according to high technical and regulatory safety standards and operate at comparatively low pressures of around 2 bar. Furthermore, the hazard potential of a pressure vessel depends not only on pressure but also significantly on volume; the volume of dental practice autoclaves—typically 17 to 30 liters—is very low compared to pressure vessels used in commercial and industrial settings. Regular maintenance carried out in accordance with manufacturer specifications (usually annually or at intervals defined by the manufacturer) involves checking all relevant components—such as sensors, safety valves, and seals—as well as system integrity, thereby ensuring safe operation. During this maintenance, the pressure vessel undergoes visual and functional inspections; more extensive, in-depth testing of the vessel itself is neither performed nor recommended by manufacturers. Existing literature regarding autoclave incidents in dental and medical facilities focuses on sterilization failures and microbiological contamination rather than mechanical pressure vessel failures or explosions. No studies have been identified that report serious incidents involving the pressure vessel itself (such as explosions, ruptures, or structural failures). The lack of evidence regarding pressure vessel issues suggests that such incidents are extremely rare, likely due to stringent technical safety standards and mandatory regular maintenance. That covers the topic in some detail from a Swiss perspective.*
Latvia	There is any check up based on the age of sterilizer.
Austria	For further information: in Austria, the chamber´s new hygiene regulation stipulates that every dental practice must have a Class B sterilizer. There is a three-year transition period for existing dental practices, i.e. until 1 May 2028.

United Kingdom	There is the Pressure Systems Safety Regulations 2000: Pressure Systems Safety Regulations 2000 (PSSR) - HSE https://www.hse.gov.uk/pressure-systems/pssr.htm Separately, there are national decontamination guidance documents (England, Northern Ireland, Scotland, Wales) – which include testing recommendations - we are not aware of these referring to equipment timeframes.
Iceland	Spore tests are carried out by the dental clinic as part of its routine quality assurance procedures, regardless of the age of the sterilizer. The indicator is sent to the microbiology laboratory at Landspítali – The National University Hospital of Iceland, where it is incubated and analysed. The results confirm whether the sterilization process has been effective.

Council of European Dentists
President Dr. Freddie Sloth-Lisbjerg
Transparency register: 4885579968-84
Numéro d'entreprise: 0480.222.749
Avenue de Cortenbergh 89/6
B-1000 Brussels
T +32 (0)2 736 34 29
ced@cedentists.eu
www.cedentists.eu