



# SLOVENSKI STANDARD

## SIST EN 13060:2025

01-oktober-2025

Nadomešča:

SIST EN 13060:2015+A1:2019

---

**Sterilizatorji za uporabo v medicini - Mali parni sterilizatorji - Zahteve in preskušanje**

Sterilizers for medical purposes - Small steam sterilizers - Requirements and testing

Sterilisatoren für medizinische Zwecke - Dampf-Klein-Sterilisatoren - Anforderungen und Prüfung

Stérilisateur à usage médical - Petits stérilisateur à la vapeur d'eau - Exigences et essais

**Ta slovenski standard je istoveten z: EN 13060:2025**

<https://ecommerce.sist.si/catalog/standards/sist/cb4a2370-36b9-4c29-be66-ce8411eb258e/sist-en-13060-2025>

---

**ICS:**

11.080.10      Sterilizacijska oprema      Sterilizing equipment

**SIST EN 13060:2025**

**en,fr,de**



EUROPEAN STANDARD

EN 13060

NORME EUROPÉENNE

EUROPÄISCHE NORM

August 2025

ICS 11.080.10

Supersedes EN 13060:2014+A1:2018

English Version

## Sterilizers for medical purposes - Small steam sterilizers - Requirements and testing

Stérilisateurs à usage médical - Petits stérilisateurs à la  
vapeur d'eau - Exigences et essais

Sterilisatoren für medizinische Zwecke - Dampf-Klein-  
Sterilisatoren - Anforderungen und Prüfung

This European Standard was approved by CEN on 23 June 2025.

CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Türkiye and United Kingdom.

[SIST EN 13060:2025](https://ecommerce.sist.si/catalog/standards/sist/cb4a2370-36b9-4c29-be66-ce8411eb258e/sist-en-13060-2025)

<https://ecommerce.sist.si/catalog/standards/sist/cb4a2370-36b9-4c29-be66-ce8411eb258e/sist-en-13060-2025>



EUROPEAN COMMITTEE FOR STANDARDIZATION  
COMITÉ EUROPÉEN DE NORMALISATION  
EUROPÄISCHES KOMITEE FÜR NORMUNG

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

<b>Contents</b>	<b>Page</b>
European foreword.....	6
Introduction .....	8
<b>1 Scope</b> .....	<b>9</b>
<b>2 Normative references</b> .....	<b>9</b>
<b>3 Terms and definitions</b> .....	<b>11</b>
<b>4 General</b> .....	<b>23</b>
4.1 Product definition.....	23
4.2 Equipment development .....	24
4.3 Calibration.....	24
<b>5 Equipment design and construction</b> .....	<b>25</b>
5.1 Safety and security.....	25
5.1.1 General requirements .....	25
5.1.2 Electromagnetic interference.....	26
5.1.3 Risk control and usability .....	26
5.2 Chamber .....	27
5.2.1 Dimensions.....	27
5.2.2 Doors.....	27
5.2.3 Chamber integrity.....	28
5.2.4 Pressure vessels .....	28
5.2.5 Uniformity of conditions.....	28
5.2.6 Ancillary equipment and components .....	28
5.3 Materials.....	29
5.4 Interlocks .....	29
5.5 Test connections.....	30
5.6 Vibration .....	30
5.7 User interfaces .....	31
5.8 Transport.....	31
<b>6 Indicating, monitoring, controlling and recording</b> .....	<b>32</b>
6.1 General.....	32
6.2 Automatic control .....	32
6.3 Software.....	33
6.4 Control and monitoring system .....	34
6.5 Failure .....	35
6.5.1 General.....	35
6.5.2 Fault .....	36
6.5.3 Power failure .....	36
6.5.4 Other failures.....	36
6.6 Instrumentation .....	37
6.7 Indicating devices .....	38
6.7.1 General.....	38
6.7.2 Sterilizer chamber temperature indicating instrument.....	38
6.7.3 Sterilizer chamber pressure instrument.....	38
6.7.4 Jacket pressure indicating instrument.....	39
6.7.5 Loading side of the sterilizer .....	39
6.7.6 Double ended sterilizer .....	40
6.7.7 Cycle counter .....	40
6.7.8 Air leak indication .....	41

<b>6.8</b>	<b>Recorders .....</b>	<b>41</b>
<b>6.8.1</b>	<b>General .....</b>	<b>41</b>
<b>6.8.2</b>	<b>Recorders producing analogue records .....</b>	<b>42</b>
<b>6.8.3</b>	<b>Recorders producing digital records .....</b>	<b>43</b>
<b>6.9</b>	<b>Process.....</b>	<b>46</b>
<b>6.9.1</b>	<b>General .....</b>	<b>46</b>
<b>6.9.2</b>	<b>Sterilization temperature, sterilization temperature band, holding time .....</b>	<b>46</b>
<b>6.9.3</b>	<b>Time-temperature relationships.....</b>	<b>46</b>
<b>6.9.4</b>	<b>Equilibration time .....</b>	<b>46</b>
<b>7</b>	<b>Services and local environment .....</b>	<b>47</b>
<b>7.1</b>	<b>General .....</b>	<b>47</b>
<b>7.2</b>	<b>Sterilizing agent and sterilant.....</b>	<b>47</b>
<b>7.3</b>	<b>Electrical supply.....</b>	<b>47</b>
<b>7.4</b>	<b>Water.....</b>	<b>47</b>
<b>7.4.1</b>	<b>General .....</b>	<b>47</b>
<b>7.4.2</b>	<b>Water supply for steam generation in the sterilizer .....</b>	<b>47</b>
<b>7.4.3</b>	<b>Water used other than for steam generation .....</b>	<b>48</b>
<b>7.5</b>	<b>Steam.....</b>	<b>48</b>
<b>7.5.1</b>	<b>External steam supply .....</b>	<b>48</b>
<b>7.6</b>	<b>Vacuum.....</b>	<b>48</b>
<b>7.7</b>	<b>Drains.....</b>	<b>48</b>
<b>7.8</b>	<b>Lighting.....</b>	<b>49</b>
<b>7.9</b>	<b>Compressed air.....</b>	<b>49</b>
<b>7.10</b>	<b>Air and inert gases.....</b>	<b>49</b>
<b>7.11</b>	<b>Ventilation.....</b>	<b>49</b>
<b>8</b>	<b>Emissions.....</b>	<b>49</b>
<b>8.1</b>	<b>Electromagnetic emissions .....</b>	<b>49</b>
<b>8.2</b>	<b>Noise.....</b>	<b>49</b>
<b>8.3</b>	<b>Heat emission.....</b>	<b>50</b>
<b>9</b>	<b>Test instrumentation .....</b>	<b>50</b>
<b>10</b>	<b>Performance and assessment .....</b>	<b>51</b>
<b>10.1</b>	<b>General .....</b>	<b>51</b>
<b>10.2</b>	<b>Chamber integrity .....</b>	<b>52</b>
<b>10.2.1</b>	<b>General .....</b>	<b>52</b>
<b>10.2.2</b>	<b>Air leakage rate .....</b>	<b>52</b>
<b>10.3</b>	<b>Attainment of conditions .....</b>	<b>52</b>
<b>10.4</b>	<b>Performance verification.....</b>	<b>53</b>
<b>10.5</b>	<b>Drying .....</b>	<b>53</b>
<b>10.6</b>	<b>Microbiological performance.....</b>	<b>53</b>
<b>10.7</b>	<b>Pressure change.....</b>	<b>53</b>
<b>10.7.1</b>	<b>General .....</b>	<b>53</b>
<b>10.7.2</b>	<b>Dynamic sterilizer chamber pressure test.....</b>	<b>54</b>
<b>11</b>	<b>Information supplied by the manufacturer .....</b>	<b>54</b>
<b>11.1</b>	<b>General .....</b>	<b>54</b>
<b>11.2</b>	<b>Information to be made available prior to purchase .....</b>	<b>54</b>
<b>11.3</b>	<b>Marking .....</b>	<b>59</b>
<b>11.3.1</b>	<b>Marking of the pressure vessel.....</b>	<b>59</b>
<b>11.3.2</b>	<b>Marking of the sterilizer and the packaging.....</b>	<b>59</b>
<b>11.4</b>	<b>Label.....</b>	<b>60</b>
<b>11.5</b>	<b>Instructions for use.....</b>	<b>60</b>
<b>11.6</b>	<b>Technical description.....</b>	<b>61</b>

## EN 13060:2025 (E)

<b>Annex A (normative) Test programme .....</b>	<b>62</b>
<b>A.1 Categories of tests .....</b>	<b>62</b>
<b>A.2 Type tests .....</b>	<b>62</b>
<b>A.3 Works test.....</b>	<b>63</b>
<b>A.4 Installation tests.....</b>	<b>63</b>
<b>A.5 Test programme .....</b>	<b>63</b>
<b>A.6 Rationale for the tests (informative) .....</b>	<b>65</b>
<b>Annex B (normative) Test equipment .....</b>	<b>68</b>
<b>B.1 Test equipment.....</b>	<b>68</b>
<b>B.2 Temperature sensors .....</b>	<b>68</b>
<b>B.3 Thermometric recording instrument.....</b>	<b>68</b>
<b>B.4 Pressure measurement and recording instrument.....</b>	<b>69</b>
<b>B.5 Test equipment for the performance of the air leakage test.....</b>	<b>70</b>
<b>B.6 Process challenge device (PCD) and chemical indicator for narrow lumen.....</b>	<b>71</b>
<b>B.7 Process challenge device and chemical indicator for simple hollow item.....</b>	<b>71</b>
<b>B.8 Balance for load dryness test.....</b>	<b>72</b>
<b>Annex C (normative) Test loads.....</b>	<b>73</b>
<b>C.1 Test loads .....</b>	<b>73</b>
<b>C.2 Porous load.....</b>	<b>73</b>
<b>C.3 Solid load, unwrapped.....</b>	<b>75</b>
<b>C.4 Solid load, single wrapped.....</b>	<b>75</b>
<b>C.5 Solid load, double wrapped .....</b>	<b>75</b>
<b>Annex D (normative) Test procedures.....</b>	<b>76</b>
<b>D.1 Test procedures .....</b>	<b>76</b>
<b>D.2 Air leakage test .....</b>	<b>77</b>
<b>D.3 Dynamic sterilizer chamber pressure test.....</b>	<b>78</b>
<b>D.4 Empty chamber test .....</b>	<b>79</b>
<b>D.5 Solid load test .....</b>	<b>79</b>
<b>D.6 Narrow lumen test .....</b>	<b>79</b>
<b>D.7 Simple hollow item test.....</b>	<b>80</b>
<b>D.8 Small porous load test .....</b>	<b>81</b>
<b>D.9 Full porous load test (single and double wrapped).....</b>	<b>82</b>
<b>D.10 Small porous items test (single and double wrapped).....</b>	<b>83</b>
<b>D.11 Solid load dryness test.....</b>	<b>84</b>
<b>D.12 Porous load dryness test (small and full, single and double wrapped) .....</b>	<b>84</b>
<b>D.13 Small porous items dryness test (single and double wrapped) .....</b>	<b>85</b>

<b>D.14</b>	<b>Microbiological test for solid loads .....</b>	<b>85</b>
<b>D.15</b>	<b>Microbiological test for narrow lumens.....</b>	<b>86</b>
<b>D.16</b>	<b>Microbiological test for simple hollow item .....</b>	<b>86</b>
<b>D.17</b>	<b>Microbiological test for small porous loads.....</b>	<b>86</b>
<b>D.18</b>	<b>Microbiological test for full porous loads.....</b>	<b>87</b>
<b>D.19</b>	<b>Microbiological test for small porous items .....</b>	<b>87</b>
<b>Annex E</b>	<b>(informative) Monitoring system .....</b>	<b>88</b>
<b>E.1</b>	<b>General .....</b>	<b>88</b>
<b>E.2</b>	<b>Principle.....</b>	<b>88</b>
<b>E.3</b>	<b>Equipment.....</b>	<b>89</b>
<b>Annex F</b>	<b>(informative) Suggested maximum limits of contaminants in and specifications for water for steam sterilization .....</b>	<b>92</b>
<b>F.1</b>	<b>Suggested maximum limits of contaminants in and specifications for water for steam sterilization.....</b>	<b>92</b>
<b>Annex G</b>	<b>(informative) Load support systems.....</b>	<b>93</b>
<b>Annex H</b>	<b>(informative) Illustrations of the interrelationship between control and recording .....</b>	<b>94</b>
<b>H.1</b>	<b>Overview.....</b>	<b>94</b>
<b>H.2</b>	<b>Illustration 1.....</b>	<b>94</b>
<b>H.3</b>	<b>Illustration 2.....</b>	<b>96</b>
<b>H.4</b>	<b>Illustration 3.....</b>	<b>97</b>
<b>Annex I</b>	<b>(informative) Environmental aspects .....</b>	<b>100</b>
<b>I.1</b>	<b>Environmental impact .....</b>	<b>100</b>
<b>I.2</b>	<b>Steam.....</b>	<b>100</b>
<b>I.3</b>	<b>Product life cycle.....</b>	<b>101</b>
<b>Annex ZA</b>	<b>(informative) Relationship between this European Standard and the General Safety and Performance Requirements of Regulation (EU) 2017/745 aimed to be covered.....</b>	<b>102</b>
<b>Bibliography</b>	<b>.....</b>	<b>120</b>