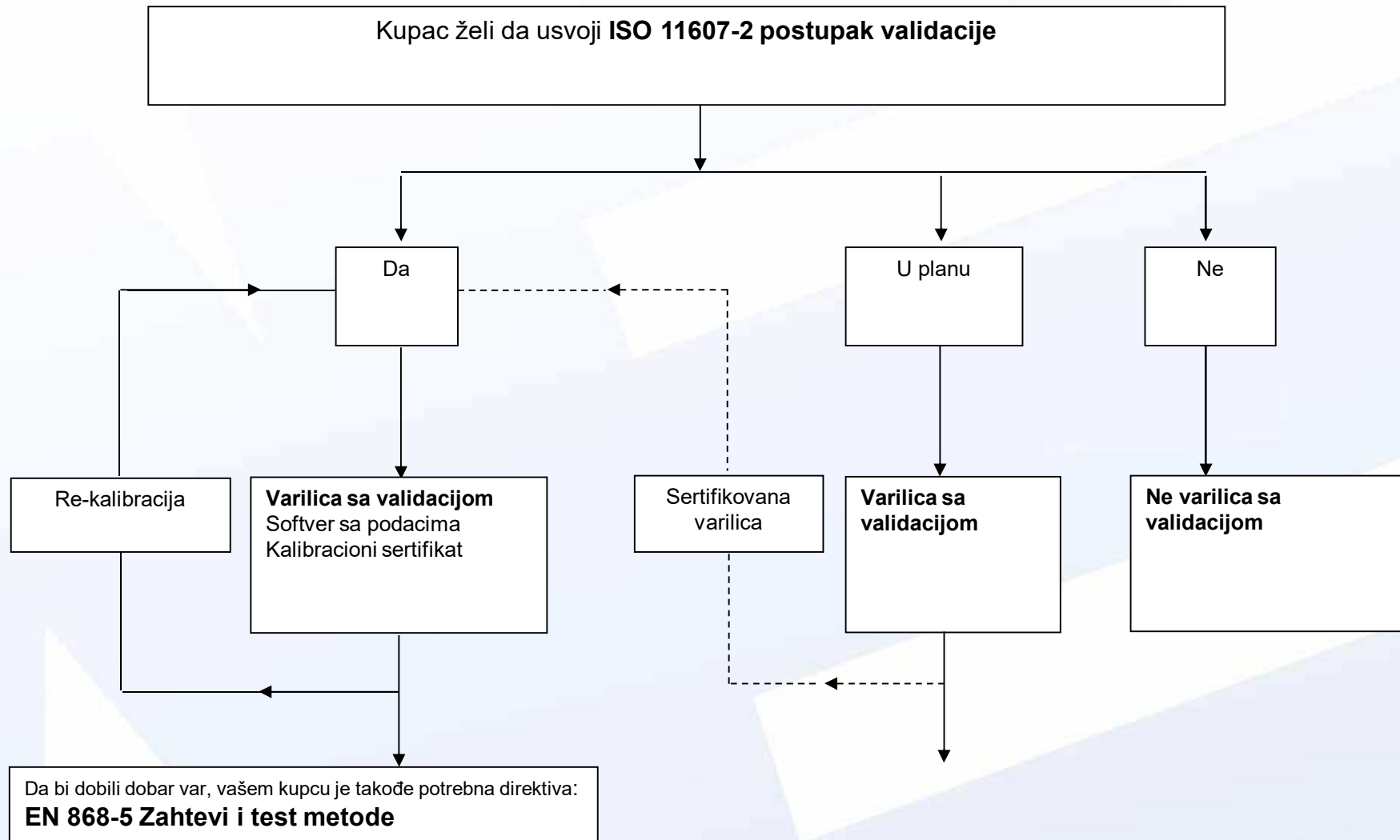




Validacija
ISO 11607-2
EN 868-5



Šta je validacija?

Postupak za uspostavljanje dokumentovanih dokaza koji obezbeđuju visok stepen uveravanja da će proces, sistem, oprema konstantno proizvoditi željeni rezultat prema unapred utvrđenim specifikacijama i karakteristikama kvaliteta

Šta ISO 11607-2 (zahtev za validaciju) znači za varilicu

- Kontrola procesa kritičnih parametara (temperatura, pritisak i brzina)
- Kritični parametri se rutinski nadgledaju i dokumentuju
- Kalibracija mašine

Zbog toga:

- Varilice sa validacijom neprekidno prate sve kritične parametre (temperaturu, pritisak i brzinu) i blokiraju mašinu kada su izvan prihvatljivih parametara
- Varilice sa validacijom mogu sačuvati sve kritične parametre. (softver za bazu podataka)
- Audion sertifikat kalibracije

Kalibracija meri tri ključne tačke procesa varenja

- Temperatura:

 - Medseal: merenje napona standardnim multimetrom

 - Contimed: upoređivanje termoosigurača sa standardnim senzorom temperature

- Pritisak: Očitavanje opterećenja standardnim težinama od 5, 10, 20 i 85kg

- Brzina / vreme:

 - Contimed: foto detekcija sa standardnim tahometrom

 - Medseal: merenje napona standardnim osciloskopom

Svi upotrebljeni standardi (merni instrumenti) moraju biti sertifikovani i imati uspostavljeno evidentiranje podataka prema (međunarodnim) nacionalnim standardima!

Calibration certificate



CALIBRATION CERTIFICATE

Doc. No. 600

Page 1 of 2 Certificate number:

Applicant data: _____
 Device under test: _____
 Applicant : _____
 Address : _____
 Place : _____
 Department : _____
 Contact : _____
 Manufacturer : Audion Elektro
 Type : 611MSIDV-2
 Serial : Seals reader
 Serial number : 18674
 Identification number : NONE
 Barcode : 162640

Used standard(s): _____
 Manufacturer : Datron _____
 Type : 1281 _____
 Expiry date : 10-Apr-2011 _____
 Certificate number : 2903984 _____
 Manufacturer : Tektronix _____
 Type : 2230 _____
 Expiry date : 2-May-2011 _____
 Certificate number : 211051408 _____

Manufacturer : _____
 Type : _____
 Expiry date : _____
 Certificate number : _____
 Weight 1: _____
 Weight 2: _____
 Weight 3: _____
 Weight 4: _____
 Manufacturer : KEERN _____
 Type : 5 kg / F1 _____
 Expiry date : 10-Feb-2011 _____
 Certificate number : 0902-01775 _____
 Manufacturer : KEERN _____
 Type : 10 kg / F1 _____
 Expiry date : 28-Jan-2011 _____
 Certificate number : 1001-06451 _____
 Manufacturer : KEERN _____
 Type : 20 kg / F1 _____
 Expiry date : 4-Sep-2010 _____
 Certificate number : 11891-0809 _____
 Manufacturer : KEERN _____
 Type : 55 kg / M1 _____
 Expiry date : 24-Mar-2012 _____
 Certificate number : 133171003 _____

Research method : The instrument is calibrated in comparison with certified reference standards.
 The calibration involves the critical parameters: the seal temperature, the seal time and the seal pressure.
 The seal temperature and the seal time are calibrated through voltage measurements by using a standard multimeter and a standard oscilloscope.
 The seal pressure is calibrated by loading the load cell with standard weights.

Environmental conditions : The temperature of the environment is 21 °C ± 3 °C.

Traceability : The measurements are undertaken with calibration equipment for which the company maintains traceability to (inter-) national standards.

Calibration started : 4-May-2010 Expiry date: 12-May-2011
 Calibration finished : 12-May-2010

Results : The results are shown on the next page(s).

Conclusion : The instrument complies with the used specifications.

Calibrated by : R. Ounjeur
 Calibration technician

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2008-02



CALIBRATION CERTIFICATE

Doc. No. 2724

Certificate number: _____
 Manufacturer : Audion Elektro
 Type : 611MSIDV-2
 Serial : Seals reader
 Serial number : 18674
 Identification number : NONE
 Barcode : 162640
 Page 2 of 2

Results :
 a) Seal temperature :

Reference T _{se} [°C]	Instrument's setting t [°C]	Deviation [°C]	Tolerance ± [°C]
100.20	100	0.20	1.0
150.66	150	0.66	1.5
250.47	250	0.47	2.5

Tolerance : The maximum allowed deviation for the seal temperature is ± 1% of the instrument's settings.

Conclusion : The seal temperature complies with the used specification.

b) Seal time :

Reference [sec]	Instrument's setting [sec]	Deviation [sec]	Tolerance ± [sec]
1.00	2.0	0.00	0.3
2.01	2.0	0.01	0.3
3.02	3.0	0.02	0.3
4.01	4.0	0.01	0.3
5.01	5.0	0.01	0.3
6.01	6.0	0.01	0.3

Tolerance : The maximum allowed deviation for the seal time is ± 0.3 seconds of the setpoint.

Conclusion : The seal time complies with the used specification.

c) Seal pressure :

Reference [N]	Instrument's reading [N]	Deviation [N]	Tolerance ± [N]
48.95	49	0.05	2
98.10	98	0.10	4
196.20	197	-0.80	8
833.85	834	-0.15	32

Tolerance : The maximum allowed deviation for the seal pressure is ± 4% of the instrument's reading.

Conclusion : The seal pressure complies with the used specification.

Table presentation :
 1. The reference value;
 2. The setting / reading of the instrument under test;
 3. The deviation is the reference value minus the settings / reading of the instrument under test;
 4. The maximum allowed deviation of the instrument under test.

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2008-02

AE AUDION

Packaging machines

CALIBRATION CERTIFICATE

Doc. Nr: 6901

Page 1 of 2

Certificate number:

Applicant data:

Applicant :
 Address :
 Place :
 Department :
 Contact :

Device under test:

Manufacturer : Audion Elektro
 Type : 611MSIDV-2
 Sort : Static sealer
 Serial number : 18674
 Identification number : NONE
 Barcode : 162640

Used standard(s):

Manufacturer : Datron
 Type : 1281
 Expiry date : 10-Apr-2011
 Certificate number : 29009581

Manufacturer : Tektronix
 Type : 2230
 Expiry date : 2-May-2011
 Certificate number : 2110011408

	Weight 1:	Weight 2:	Weight 3:	Weight 4:
Manufacturer :	<u>KERN</u>	<u>KERN</u>	<u>KERN</u>	<u>EEGEMA</u>
Type :	<u>5 Kg / F1</u>	<u>10 kg / F1</u>	<u>20 kg / F1</u>	<u>85 kg / M1</u>
Expiry date :	<u>10-Feb-2011</u>	<u>28-Jan-2011</u>	<u>4-Sep-2010</u>	<u>22-Mar-2012</u>
Certificate number :	<u>0902-01775</u>	<u>1001-06451</u>	<u>11891-0809</u>	<u>13317/1003</u>

Research method : The instrument is calibrated in comparison with certified reference standards.
The calibration involves the critical parameters: the seal temperature, the seal time and the seal pressure.
The seal temperature and the seal time are calibrated through voltage measurements by using a standard multimeter and a standard oscilloscope.
The seal pressure is calibrated by loading the load cell with standard weights.

Environmental conditions : The temperature of the environment is $21\text{ }^{\circ}\text{C} \pm 3\text{ }^{\circ}\text{C}$.

Traceability : The measurements are undertaken with calibration equipment for which the company maintains traceability to (inter-) national standards.

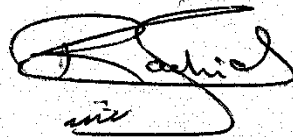
Calibration started : 4-May-2010
Calibration finished : 12-May-2010

Expiry date: 12-May-2011

Results : The results are shown on the next page(s).

Conclusion : The instrument complies with the used specifications.

Calibrated by : R. Oujjeyr
Calibration technician



Results :

a) Seal temperature :

Reference t_{90} [°C]	1	Instrument's setting t [°C]	2	Deviation [°C]	3	Tolerance \pm [°C]	4
100.20		100		0.20		1.0	
150.66		150		0.66		1.5	
250.47		250		0.47		2.5	

Tolerance : The maximum allowed deviation for the seal temperature is $\pm 1\%$ of the instrument's settings.

Conclusion : The seal temperature complies with the used specification.

b) Seal time :

Reference [sec]	1	Instrument's setting [sec]	2	Deviation [sec]	3	Tolerance \pm [sec]	4
1.00		1.0		0.00		0.3	
2.01		2.0		0.01		0.3	
3.02		3.0		0.02		0.3	
4.01		4.0		0.01		0.3	
5.01		5.0		0.01		0.3	
6.01		6.0		0.01		0.3	

Tolerance : The maximum allowed deviation for the seal time is $\pm 0,3$ seconds of the setpoint.

Conclusion : The seal time complies with the used specification.

c) Seal pressure

Reference [N]	1	Instrument's reading [N]	2	Deviation [N]	3	Tolerance ± [N]	4
49.05		49		0.05		2	
98.10		98		0.10		4	
196.20		197		-0.80		8	
833.85		834		-0.15		33	

Tolerance : The maximum allowed deviation for the seal pressure is $\pm 4\%$ of the instrument's reading.

Conclusion : The seal pressure complies with the used specification.

Table presentation :
1. The reference value;
2. The setting / reading of the instrument under test;
3. The deviation is the reference value minus the settings / reading of the instrument under test;
4. The maximum allowed deviation of the instrument under test.

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Kada je potrebna kalibracija?

- Rutinski. Prema procedurama koje kupac poseduje. Preporučujemo kalibraciju jednom godišnje
- Kad god se vrše izmene vezane za proces, to može uticati na status procesa validacije

Informacije o kalibraciji:

- Kalibracija traje 3 do 4 nedelje. (transport, provera mašina, kalibracija i transport nazad)
- Kalibracija se vrši u ovlašćenoj laboratoriji za kalibraciju
- Korisnik dobija zvanični Audion sertifikat kalibracije

Šta EN 868-5

(zahtevi i test metoda) podrazumeva?

- Parametri varenja (samo kvalifikovano osoblje)
- Test izdržljivosti vara (jačina vara)

Test jačine vara



Dinamometar

- Jačina izdržljivosti vara:
 - Mora biti $\geq 1,5$ N
 - 15mm širina (test trake)
 - I pre i nakon što su podvrgnuti procesu sterilizacije

Tržišta

- Medicinsko
- Farmaceutsko
- Laboratorije
- Hemijsko

Medicinsko / farmaceutsko tržište

- Vrlo jaka finansijska situacija (dobre marže, bez recesije).
- Rastuće tržište (mnogo investicija).
- Veliko tržište znanja (teško je ući u konkurenciju)

Jedinstvene tačke prodaje

Audion usluga kalibracije :

- Prodaja, održavanje i kalibracija na jednoj adresi
- Kalibracija u zvaničnoj laboratoriji
- Zvanični Audion kalibracioni sertifikat

Vreme za pitanja

- Pitanje?