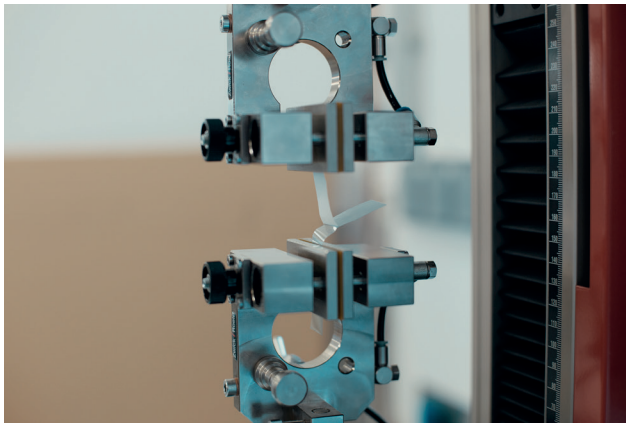


Seal seam stability test for MELAG sealing devices

Annual routine control for the validation of packaging processes in accordance with DIN EN ISO 11607-2



We recommend an annual routine check of the sealing seam stability as validation of the packaging processes and performance qualification (PQ).

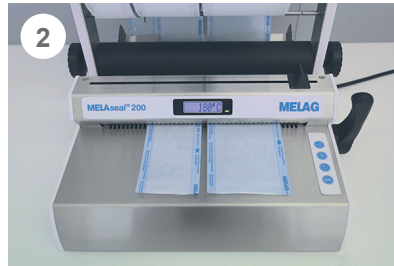
The seal seam stability test is a standardized test procedure. A successful test is recorded on a MELAG certificate stating conformity of the seal seam with DIN EN 868-5, appendix D.

Further information about this topic is available from the MELAG website (www.melag.de) under Products/Packaging.

Instructions for making a test strip



1 Cut three 10 cm test strips from the smallest packaging format used in the practice.



2 Cut a 10 cm long test strip from every wider format.



3 All test strips must have two seal seams separated by a gap of 5 cm.



4 Mark all test strips with a sequential number.



5 Sterilize all test strips in your steam sterilizer using the Universal program (134°C).



6 Complete the following form and send it to MELAG together with the test strips.

MELAG Medizintechnik oHG
Seal seam stability test
Geneststraße 6-10
10829 Berlin

Please complete and send the application form together with the test film strips to MELAG in a DIN A4 envelope with sufficient postage.

Application form for seal seam stability test

We hereby commission a seal seam stability test of the sealing device specified below using the test film strips included. This test costs 125.00 € plus VAT (as of 01/2017).

Date

Client signature

Contact information

Practice/clinic

Name of the practice/clinic

Contact person

Street/house number

Post code/town

Country

e-mail

Telephone for queries (with country code)

Billing address

(If different from the practice address)

Name of the practice/clinic

Contact person

Street/house number

Post code/town

Country

e-mail

Telephone for queries (with country code)

Sealing device/process parameters

MELAseal 100+ MELAseal 200 MELAseal Pro MELAseal 100/101/103

Serial number of the sealing device _____

The seal seam test seals were generated using the following sealing device settings:

Thermostat setting/ sealing temperature [°C]	_____ °C/level	Sealing force ¹⁾ [in N]	_____ N
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The seal seam of the test seams were sterilized in the following steam sterilizer:

Device type	_____	Manufacturer	_____
Serial no.	_____		

Test film strips used

List all test strips (specifying type and width) sent in in the following table:

No.	Film manufacturer/designation	Width of the test strip [in cm]	Expiry date/ LOT no. of the film ²⁾
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

1) Only for MELAseal 200 and MELAseal Pro

2) The expiry date for MELAfol is listed on the corresponding transport packaging. The MELAfol LOT no. is to be found on the paper side. If no specification is possible, leave the column blank. In such a case, check that the manufacturer's expiry date has not been exceeded. Details are to be found on the product data sheet of the film.