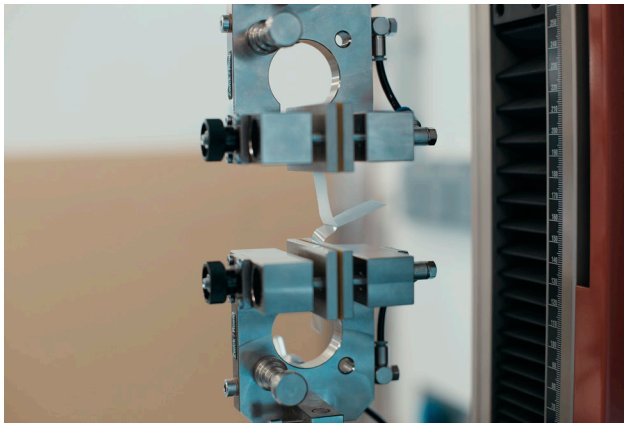


Seal seam stability test for MELAG sealing devices

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).

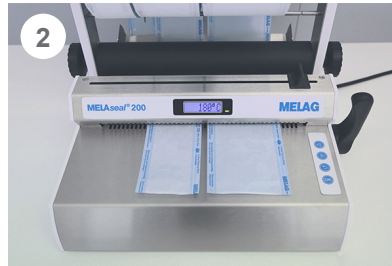
The seal seam stability test is a standardized test procedure. A successful test is recorded on a MELAG certificate stating conformity of the seal seam with DIN EN 868-5, appendix D.

Further information about this topic is available from the MELAG website (www.melag.com) 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 GmbH & Co. KG
Seal seam stability test
Geneststraße 6-10
10829 Berlin

Please complete 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 01/2020).

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 [in N] (only for MELAseal 200 and MELAseal Pro)	_____ 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 ¹⁾
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			

1) 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 a column free. 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.