Dürr Dental Service

Hygopac Plus – annual seal-seam test (performance evaluation) for sealing devices in acc. with EN ISO 11607-2

The integrity of the seal on transparent sterile-goods packaging must be verified by an annual test known as PQ = Performance Qualification. "Process validation" is understood as provision of objective verification in acc. with Standard EN ISO 11607-2 that all quality requirements have been met.

Quick and easy quality confirmation

The Performance Qualification involves, on the one hand, use of a proper packaging and materials system and on the other, double-checking the seal seam for tensile strength in acc. with standard test procedures.

Dürr Dental offers dental surgeries this seal-seam test as a service for the foil-sealing unit Hygopac Plus under article number 0000-500. Each purchase of a new Dürr Dental Hygopac Plus includes a 1-year certificate for free Hygofol products. For a price of € 115.00, quality will be retested and performance qualified, forming an important component of internal quality control.

Hygofol sterile-goods packaging with visible 12-mm wide seal seam for utmost safety

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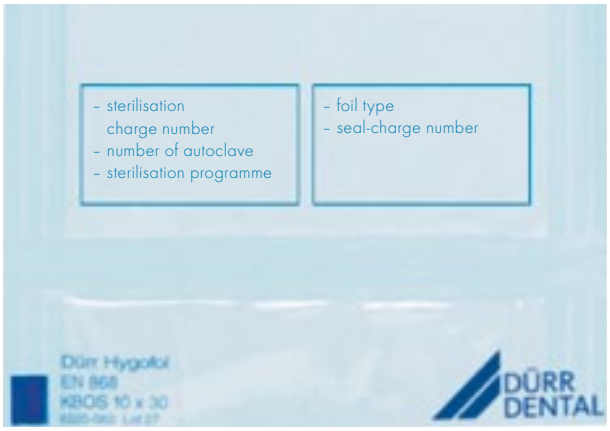
THE BEST, BY DESIGN

How do I proceed?

1. Please prepare three samples each per foil type. For rolled goods please cut off a length of 30 cm.
2. Seal the foil samples prepared in this way on the open side. For rolled goods, please seal both open ends.
3. Note down the sealing parameters (sealing temperature, tensile strength and sealing speed) for the foil samples in the included checklist. You will find the parameters by clicking on the menu button and selecting the sealing parameters (see also the Hygopac Plus instructions for use).
4. Sterilise the sealed samples in your autoclave. Add a separate sterilisation charge by foil type to each of the three samples (Sample 1 in Charge 1, Sample 2 in Charge 2, Sample 3 in Charge 3). Please label each sample as depicted in the image below.
5. Please completely fill out the included form, the checklist and the order and send them, incl. the foil samples, to us. Please make sure that the foil samples are not bent or folded.



What does "foil type" mean?

Any transparent sterile-goods packaging that is sealed with Hygopac Plus and varies according to size, manufacturer, rolled or bagging goods, lateral folds, etc., constitutes a different type of foil.

Sterilisation of foil samples

Select the Universal programme for packaged instruments 134°C for sterilising samples. If you also use other programmes for sterilising packaged instruments, also prepare three samples each for the other sterilisation programmes and sterilise these as well in 3 different sterilisation charges (Sample 1 in Charge 1, Sample 2 in Charge 2, Sample 3 in Charge 3).

Please label the samples on the foil side, do not place labels on the seal seams and use appropriate markers for labelling (DIN 58953-7). Please ensure that the sterilisation processes have been successfully completed.

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Sealed-seam test

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Device name/serial number

Test sample (manufacturer and format of steriliser packaging)

Sterilised with (device, description, manufacturer of steriliser)

Surgery stamp

Hello,

We hereby authorise DÜRR DENTAL SE to conduct the seal-seam test, at a price of € 115.00 (plus VAT), of the foil sealing device mentioned above and based on the test samples sent in by us.

Customer signature Date

Preparation of samples and documentation for Performance Qualification in acc. with DIN EN ISO 11607-2

Hygopac Plus check list for annual Performance Qualification
Please mark the box indicating which sterilisation programme will sterilise which foil material.
If more than 6 foil types (A, B, C, etc.) are used, please copy the form.

Hygopac Plus Sealing device no.	Steam sterilisation		
	Universal programme 134°	Regular programme 134°	Gentle programme; i.e. plastics programme 121°
Foil type A	☐	☐	☐
Foil type B	☐	☐	☐
Foil type C	☐	☐	☐
Foil type D	☐	☐	☐
Foil type E	☐	☐	☐
Foil type F	☐	☐	☐

Required fields

☐ I hereby confirm the terms and conditions of Dürr Dental SE. The Terms and Conditions can be viewed at ›› **www.duerrdental.com**. Unless you are the owner and/or authorised operator of such devices, registration may only be carried out with the express consent of the owner and/or authorised operator.

☐ I consent to the data that I have provided in the contact form above being collected, processed, stored and used for order processing and customer service purposes. Additionally, I consent to Dürr Dental SE passing the data I that have provided in the contact form above on to Group companies ›› **www.duerrdental.com/en/company/duerr-dental-se-subsidiaries** (or to companies associated with Dürr Dental).

Date, Signature

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Seal-Seam Test

Preparation of samples and documentation for Performance Qualification in acc. with DIN EN ISO 11607-2

Hygopac Plus process parameters
Please fill in the table with the sealing parameters per foil.
If more than 6 foil types (A, B, C, etc.) are used, please copy the form.

	Foil type A	Foil type B	Foil type C
Hygopac Plus	**Process parameters**	**Process parameters**	**Process parameters**
Sealing temperature			
Tensile strength			
Sealing speed			

	Foil type D	Foil type E	Foil type F
Hygopac Plus	**Process parameters**	**Process parameters**	**Process parameters**
Sealing temperature			
Tensile strength			
Sealing speed			

Check list for Performance Qualification in acc. with DIN EN ISO 11607-2

1.	Three samples each per foil type prepared for sealing (for rolled goods a length of 30 cm)?	☐
2.	Produced samples sealed and sealing temperature noted on form?	☐
3.	Programmes used for sterilising packaged instruments determined and marked on form?	☐
4.	Three samples each per foil type sterilised in 3 different sterilisation charges?	☐
5.	Sterilisation protocol monitored, sterilisation process successfully completed?	☐
6.	Sealed and subsequently sterilised samples labelled (foil type, seal-charge number, sterilisation programme, number of autoclave and charge number)?	☐
7.	Attached documents completely filled out and securely packed together with the produced samples?	☐

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