

# Dürr Dental Service

Hygopac - annual sealed seam test (for performance) for sealing devices in acc. with EN ISO 11607-2

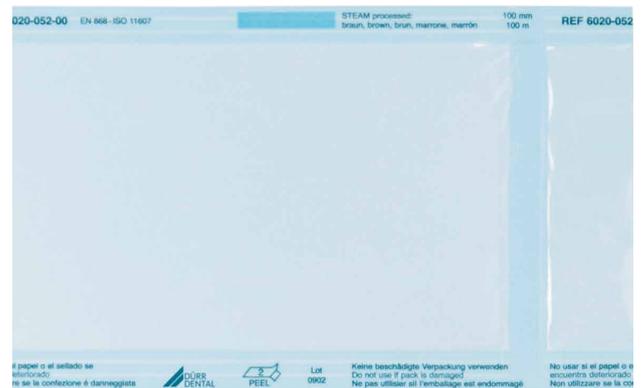
The seal integrity of transparent sterile packaging must be verified by an annual test known as the PQ = Performance Qualification. "Process validation" is understood as provision of objective verification, having met all quality requirements in acc. with Standard EN ISO 11607-2.



## 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 under article number 0000-500. Each purchase of a new Dürr Dental Hygopac includes a 1-year certificate for free Hygofol products. For a price of € 120.00 (plus VAT, Prices according to price list 2021), quality will be retested and performance qualified, forming an important component of internal quality control.



Hygofol sterile-goods packaging with visible 9-mm wide seal seam for utmost safety

## 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. To record the seal temperature please sketch the position of the temperature controller onto the included checklist.
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 Hygopak and varies according to size, manufacturer rolled or bagging goods, lateral folds, etc., constitutes a different type of foil.

## Sterilisation of test samples

Select the Universal programme for packaged instruments 134°C for sterilising samples. If you also use other programmes or 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.

Find out more online at the Deutsche Gesellschaft für Sterilgutversorgung e. V. at [www.dgsv-ev.de](http://www.dgsv-ev.de)

# Order seal-seam test

DÜRR DENTAL SE  
- Service -  
Pleidelsheimer Str. 36  
74321 Bietigheim-Bissingen  
tel. +49 (0)7142/705-480  
fax +49 (0)7142/705-230

Device name/serial number

Test sample (manufacturer and format of steriliser packaging)

Sterilised with (device, description, manufacturer of steriliser)

Hello,

We hereby authorise DÜRR DENTAL SE to conduct the seal-seam test, at a price of € 120.00 (plus VAT, Prices according to price list 2021), of the foil sealing device mentioned above and based on the test samples sent in by us.

Surgery stamp

Signature

Date

## Sample preparation and documentation for Performance Qualification in acc. with DIN EN ISO 11607-2

### Hygopac checklist for annual performance evaluation

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 Sealing device no.	Steam sterilisation		
	Universal programme 134°	Regular programme 134°	Gentle programme, i.e. plastics programme 121°
Foil type A	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Foil type B	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Foil type C	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Foil type D	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Foil type E	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Foil type F	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

### Required fields

- I hereby confirm the terms and conditions of Dürr Dental SE. The Terms and Conditions can be viewed at » [www.duerrdental.com](http://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](http://www.duerrdental.com/en/company/duerr-dental-se-subsidiaries) (or to companies associated with Dürr Dental).

Date, Signature

# Seal-Seam Test

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



### Hygopac process parameters

Please mark the position of the temperature selection switch per foil type, as shown in the image.  
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	Process parameters	Hygopac	Process parameters	Hygopac	Process parameters
	Please sketch the position of your temperature selection switch onto the image.		Please sketch the position of your temperature selection switch onto the image.		Please sketch the position of your temperature selection switch onto the image.

Foil type D		Foil type E		Foil type F	
Hygopac	Process parameters	Hygopac	Process parameters	Hygopac	Process parameters
	Please sketch the position of your temperature selection switch onto the image.		Please sketch the position of your temperature selection switch onto the image.		Please sketch the position of your temperature selection switch onto the image.

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

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