

# Order Form

# Biocompatibility

Please  
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Previous Quotation No.: (if available)

Laboratory's Use Only:

Report No.:

Due Date:

## Customer: (only fill in if different from the offer)

Company Name:	
Street, No.:	
Postal Code:	City:
Country:	
VAT-No:	Commercial Register:
Contact: <input type="checkbox"/> Mr. <input type="checkbox"/> Mrs.	First Name:
Position:	
Phone:	E-Mail:
Surname:	

## Invoice Recipient: (only if different from the customer)

Address:
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## Information Sample Material: (Data for the test report)

Name/Designation:	
Trade Name:	Article No.:
Composition:	
Colour/Quality:	
Batch/Serial No/Lot:	
UDI (if applicable):	
Manufacturer:	
Date of Manufacture:	
Expiry Date (if applicable):	
Type of Product/End Use Purpose:	
Medical Device:	<input type="checkbox"/> No <input type="checkbox"/> Yes if yes - class:
Number of Products Submitted:	
Other Information: (e.g. information on any pre-treatment carried out, instructions on storage and handling conditions, warnings)	

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<b>Sample preparation information:</b> (if applicable)	
<input type="checkbox"/> Product/test sample is sterile	
<input type="checkbox"/> Sterilisation/decontamination by the testing laboratory is requested:	
<input type="checkbox"/> Pre-treatment sterilization	<input type="checkbox"/> Pre-treatment UV radiation
<input type="checkbox"/> Care treatment by the testing laboratory is requested:	
Washing Procedure:	Drying Method:
Other:	

Test parameters:	
Ordering individual tests	Extractives
<input type="checkbox"/> Cytotoxicity (DIN EN ISO 10993-5)	<input type="checkbox"/> Artificial perspiration solution <input type="checkbox"/> Cell culture medium <i>(Please provide sterile products if possible!)</i>
<input type="checkbox"/> Cytotoxicity for textiles containing elastane (DIN EN ISO 10993-5 in combination with Wiegand et al., 2017)	<input type="checkbox"/> Artificial perspiration solution
<input type="checkbox"/> Irritation on the reconstructed human epidermis model (DIN EN ISO 10993-23) <i>(Please provide sterile products if possible!)</i>	<input type="checkbox"/> NaCl and sesame oil
<input type="checkbox"/> Chemical characterisation (DIN EN ISO 10993-18)  <i>(Please also fill in the information on the test item on page 3).</i>	<input type="checkbox"/> n-hexane <input type="checkbox"/> Methanol <input type="checkbox"/> Isopropanol <input type="checkbox"/> EtOH/water mixture <input type="checkbox"/> Other <i>(on request)</i>
<input type="checkbox"/> Sensitisation for consumer goods (Screeningtest, Hohenstein Method)	<input type="checkbox"/> Artificial perspiration solution
<input type="checkbox"/> Sensitisation for medical devices (DIN EN ISO 10993-10 Annex C)  <input type="checkbox"/> Key event 1 Covalent binding to skin proteins: Direct Peptide Reactivity Assay (DPRA)  <input type="checkbox"/> Key event 2 Keratinocyte response: IL-18 RhE-Test  <input type="checkbox"/> Key event 3 Activation of dendritic cells: U937 Cell Line Activation Test (U-SENS™)	<input type="checkbox"/> Water <input type="checkbox"/> Acetonitrile <input type="checkbox"/> Other <i>(on request)</i>  <input type="checkbox"/> NaCl and sesame oil <i>(Please provide sterile products if possible!)</i>  <input type="checkbox"/> Cell culture medium <i>(Please provide sterile products if possible!)</i> <input type="checkbox"/> Artificial perspiration solution
<input type="checkbox"/> HET-CAM (DB-ALM protocol no 96:2010-02)	<input type="checkbox"/> Artificial perspiration solution

<b>Order Management:</b> * Depending on the service requested & upon confirmation by the lab if the samples are received prior to 10 am.	
Priority:	<input type="checkbox"/> <b>Regulär</b> (10-25 working days*) <input type="checkbox"/> <b>Express</b> (50% express fee – 5-10 working days* (exception: irritation, Sensitisation for medical devices))
Test report language:	<input type="checkbox"/> <b>GERMAN &amp; ENGLISH</b> (Further languages on demand)
Return of remaining test specimen:	<input type="checkbox"/> No <input type="checkbox"/> Yes (chargeable)
Send report by:	<input type="checkbox"/> E-Mail <input type="checkbox"/> Additional report recipient: <input type="checkbox"/> Postage to: <input type="checkbox"/> Customer (as above) <input type="checkbox"/> Invoice recipient (as above) <input type="checkbox"/> Other:

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Test item – clinical contact information	
Description of the intended clinical use	(if not given on page 1)
Clinical exposure (items used per day)	(number of) devices/day
Cumulated contact duration	<input type="checkbox"/> limited < 24 hours <input type="checkbox"/> prolonged 24 hours – 30 days <input type="checkbox"/> long-term > 1 month – 12 months <input type="checkbox"/> long-term > 1 year – 10 years <input type="checkbox"/> long-term > 10 years
TTC (threshold of toxicological concern), daily intake	<input type="checkbox"/> µg/day <input type="checkbox"/> not available
AET (analytical evaluation threshold)	AET value for GC/MS is available <input type="checkbox"/> yes µg/ml <input type="checkbox"/> no

Note: If the AET is below the LOD (limit of quantification), only analytes above LOD (0.1 µg/ml) can be reported. Extract concentration is only possible considering that volatile substances may be lost by this process and are underrepresented in the analytical result.

I wish to have the product extract concentrated if the calculated AET value is below the LOD.

Test item – extraction information	
Weight of the whole product	(If test item is the whole product, parameter will be varified by the lab)
Extraction conditions	<input type="checkbox"/> 37°C for 24 h (simulated conditions of use) <input type="checkbox"/> 37°C for at least 3x 24 h (exhaustive conditions) <input type="checkbox"/> other

Comments:

Contact:			
Administrative support:	E-Mail: customerservice@hohenstein.com	Technical support:	E-Mail: medical@hohenstein.com
	Phone: +49 (0)7143-271 898		Phone: +49 (0)7143-271 440

By entering your name on the line below and submitting this information to Hohenstein Laboratories GmbH & Co. KG, you confirm that all the information contained in this document is, to the best of your knowledge, in accordance with the facts and may be used by Hohenstein Laboratories GmbH & Co. KG for the performance of the approved tests and the preparation of the corresponding test report.

Date \_\_\_\_\_

Authorized Signature, Name in Print, Company Stamp (if available)

**DISPATCH OF TEST SAMPLES: Please follow our shipping instructions below!**

**1**



PRINT OUT quotation & order form.

**2**



SIGN order form, add company stamp.

**3**



PLACE quotation & order form in the package.

**4**



SEND package to:  
Hohenstein Laboratories GmbH & Co. KG  
Arrival Medical  
Schlosssteige 1 · 74357 Bönnigheim · Germany

**IMPORTANT**  
Please mark the side of the test sample facing the skin!