

# Certificate of Approval

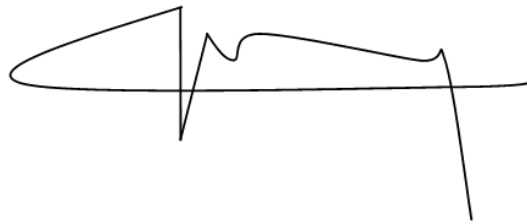
This is to certify that the Management System of:

## Dr. P. E. DELIBALTAS Ltd Electrochem

Industrial area of Thessaloniki, Sindos, 57022 Thessaloniki, Greece

has been approved by LRQA to the following standards:

**BS EN ISO 9001:2015**



Gilles Bessiere - Area Technical Manager

Issued By: Hellenic Lloyd's S.A.

for and on behalf of: Lloyd's Register Quality Assurance Limited

This certificate forms part of the approval identified by approval number: 0028961

Current Issue Date: 28 May 2018

Original Approvals:

Expiry Date: 27 May 2021

ISO 9001 – 16 May 2018

Certificate Identity Number: 10083449

Approval Number(s): ISO 9001 – 0028961-001

The scope of this approval is applicable to:

Design, production and supply of elastomers and speciality polymers for medical and industrial use.



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# Certificate of Approval

This is to certify that the Management System of:

## Dr. P. E. DELIBALTAS Ltd Electrochem

Industrial area of Thessaloniki, Sindos, 57022 Thessaloniki, Greece

has been approved by LRQA to the following standards:

EN ISO 13485:2016



Gilles Bessiere - Area Technical Manager

Issued By: Hellenic Lloyd's S.A.

for and on behalf of: Lloyd's Register Quality Assurance Limited

This certificate forms part of the approval identified by approval number: 0028960

Current Issue Date: 28 May 2018

Expiry Date: 27 May 2021

Certificate Issue Number: 10083476

Original Approvals:

ISO 13485 16 May 2018

Approval Certificate Number: ISO 13485 – 0028960-001

The scope of this approval is applicable to:

Design, production and supply of elastomers and speciality polymers for medical use.



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**DECLARATION OF CONFORMITY  
ÜBEREINSTIMMUNGSERKLÄRUNG**



MANUFACTURER / HERSTELLER

AUTHORIZED REPRESENTATIVE /  
OFFIZIELER VERTRETER  
(established in the EC / eingesetzt in EC)

Dr DELIBALTAS Ltd - electrochem®	SUPERCO GmbH
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ADDRESS / ADRESSE

ADDRESS - ADRESSE

INDUSTRIAL AREA THESSALONIKI DA11 STR. - 39A BLOCK P.O. 57022 SINDOS – HELLAS	AM BRUNNENLECH 3 86150 AUGSBURG BAYERN - GERMANY
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HEREWITH DECLARES THAT / HIERMIT WIRD EKLÄRT DASS:  
PRODUCT'S DESCRIPTION / PRODUCTS BESCHREIBUNG

<p>TUBING OF MEDICAL GRADE SILICONE ELASTOMER (ELSIL®), YELLOW® (LATEX FREE) ELASTOMER (ELYE®) AND THERMOPLASTIC POLYMER WITH BUBBLES IN VARYING DIMENSIONS - NOT STERILISED CATEGORY I (93/42 EEC) SCHLÄUCHE MEDIZINISCHEN GRADES AUS SILIKON ELASTOMÄRE (ELSIL®), GELBES (LATEX FREI) ELASTOMÄR (ELYE®) UND THERMOPLASTISCHEN KUNSTSTOFFEN (DEVIM®) MIT UND OHNE AUSBLASUNGEN VERSCHIEDENER DIMENSIONEN – NICHT STERILIZIERT / KLASSE I (93/42 EEC)</p>
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TYPE / TYP

BRAND NAME / BEZEICHNUNG

MT, MTH, LT, VT & VB	ELSIL® / ELYE® / DEVIM® / DEVIA®
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ARE IN CONFORMITY WITH PROVISIONS OF DIRECTIVES / MIT DEN VORSCHRIFTEN DER DIREKTIVEN ÜBEREIN STIMMEN:

EN ISO 9001:2008, EN ISO 13485:2003, 93/42/EEC
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STANDARDS APPLIED BY MANUFACTURER / VORSCHRIFTEN UND NORMEN

- |  |   |
|--|---|
| <ul style="list-style-type: none"> <li>✓ Harmonized / Harmonisierte</li> <li>✓ International / Internationale</li> <li>✓ National / Nationale</li> </ul> | <p>ISO 9001, ISO 13485:2003<br/>DIN 53505/87, DIN 53517/87, ASTM D624B<br/>DY8D/1348/2004 MoH</p> |
|--|---|

YEAR IN WHICH CE MARKING WAS AFFIXED / JAHR DER "CE" KENNZEICHNUNGS AUSSTELLUNG : 2000

IDENTIFICATION OF THE PERSON EMPOWERED TO SIGN ON BEHALF OF THE MANUFACTURER  
IDENTITÄT DER ERMÄCHTIGTEN PERSON FÜR DEN HERSTELLER

NAME / NAME

SIGNATURE & MANUFACTURER'S SEAL  
UNTERSCHRIFT UND HERSTELLERSTEMPEL

EVANGELOS P. DELIBALTAS
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<p><b>Dr DELIBALTAS Ltd</b> <b>Electrochem delibaltas®</b> SILICONE ELASTOMERS &amp; SPECIALTY POLYMERS Industrial Area of Thessaloniki (Sindos) - DA11 Str - 39A Block P.O. 57022 Sindos - Thessaloniki - Hellas Tel. +30 2310 796680 - Fax: +30 2310 215236 VAT: EL 998523194</p>
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PLACE AND DATE / ORT UND DATUM

<p>22 JANUARY 2012, THESSALONIKI – HELLAS 22 JANUAR 2012, THESSALONIKI – GRIECHENLAND</p>
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