

# **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 Expiry Date: 27 May 2021 Certificate Identity Number: 10083449 Original Approvals: ISO 9001 – 16 May 2018

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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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

ADDRESS / ADRESSE

ADDRESS - ADRESSE

**INDUSTRIAL AREA THESSALONIKI** DA11 STR. - 39A BLOCK P.O. 57022 SINDOS - HELLAS

**AM BRUNNENLECH 3** 86150 AUGSBURG **BAYERN - GERMANY** 

HEREWITH DECLARES THAT / HIERMIT WIRD EKLÄRT DASS: PRODUCT'S DESCRIPTION / PRODUCTSBESCHREIBUNG

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)** 

TYPE / TYP

**BRAND NAME / BEZEICHNUNG** 

MT, MTH, LT, VT & VB

ELSIL® / ELYE® / DEVIM® / DEVIA®

ARE IN CONFORMITY WITH PROVISIONS OF DIRECTIVES / MIT DENVORSCHRIFTEN DER DIREKTIVEN ÜBEREIN STIMMEN:

EN ISO 9001:2008, EN ISO 13485:2003, 93/42/EEC

STANDARDS APPLIED BY MANUFACTURER / VORSCHRIFTEN UND NORMEN

- Harmonized / Harmonizierte
- International / Internationale
- National / Nationale

ISO 9001. ISO 13485:2003 DIN 53505/87, DIN 53517/87, ASTM D624B DY8D/1348/2004 MoH

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

uller

**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

PLACE AND DATE / ORT UND DATUM

22 JANUARY 2012, THESSALONIKI - HELLAS 22 JANUAR 2012, THESSALONIKI - GRIECHENLAND

**Dr DELIBALTAS Ltd** Electrochem delibaltas® SILICONE ELASTOMERS & SPECIALTY POLYMERS Inidustrial Anea of Thessaloniki (Sindos) - DA11 Str - 39A Block F. Ø. 570 22 Sindos - Thessaloniki - Hellas Tel. + 30/2310 196688 - Pax- + 30 2310 215236 VAT: EL 998523194