

Thessaloniki, 01 January 2018

AUTHORIZATION LETTER

To whom it may concern:

We hereby declare that,

S. C. Ecochimie S.R.L.

str. Cuza Voda, 5/1, of. 403, Chisinau MD-2060, Republica Moldova

Tel.: +373 22 52 34 32 / Fax: +373 30 55 55 96

<http://www.ecochimie.md>

is our official distributor for the territory of Republic of Moldova and therefore is authorized to promote, participate to tenders, distribute, sale and offer technical assistance for our products, as per descriptions and specifications found in our current brochure in our internet site, link :

www.electrochem.eu/images/MEDICAL_BROCHURE_EN.pdf

This authorisation is valid until December 31th, 2019.

Yours sincerely,

Dr DELIBALTAS Ltd
Electrochem delibaltas[®]
SILICONE ELASTOMERS & SPECIALTY POLYMERS
Industrial Area of Thessaloniki (Sindos) - DA 11 Str - 39^A Block
P.O. 57022 Sindos - Thessaloniki - Hellas
Tel. +30 2310 796680 - Fax: +30 2310 215236
VAT: EL 998523194

Electrochem Business Development Dept.



Certificate of Approval

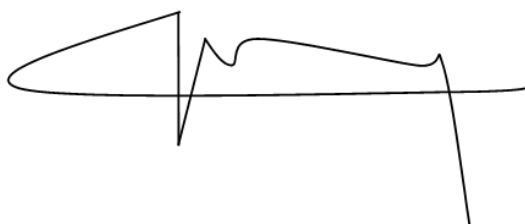
This is to certify that the Management System of:

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.



001

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

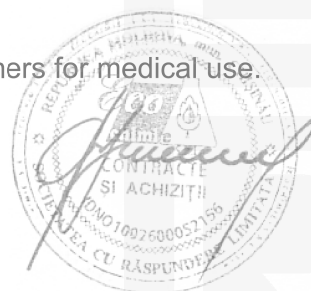
Original Approvals:

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.



001

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 / PRODUCTS BESCHREIBUNG

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 DEN VORSCHRIFTEN DER DIREKTIVEN ÜBEREIN STIMMEN:

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

STANDARDS APPLIED BY MANUFACTURER / VORSCHRIFTEN UND NORMEN

- | | | |
|---|--------------------------------|--|
| ✓ | Harmonized / Harmonisierte | ISO 9001, ISO 13485:2003 |
| ✓ | International / Internationale | DIN 53505/87, DIN 53517/87, ASTM D624B |
| ✓ | National / Nationale | DY8D/1348/2004 MoH |

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

PLACE AND DATE / ORT UND DATUM

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

Dr DELIBALTAS Ltd
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