

Certificate of Approval

This is to certify that the Management System of:

Electrochem Silicones Ltd

Industrial Area Thessaloniki (Sindos), DA 11 Str., 39A Sqr, 570 22 Thessaloniki, Greece

has been approved by Lloyd's Register to the following standards:

BS EN ISO 9001:2015

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

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

The scope of this approval is applicable to:

Design, production and supply of elastomers and speciality polymers for medical use. Provision of sterilization services according to the V-H2O2 method.



Daniel Oliva Marcilio de Souza

Area Operations Manager - South Europe

Issued by: Hellenic Lloyd's S.A.

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



Certificate of Approval

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Electrochem Silicones Ltd

Industrial Area Thessaloniki (Sindos), DA 11 Str., 39A Sqr, 570 22 Thessaloniki, Greece

has been approved by Lloyd's Register to the following standards:

EN ISO 13485:2016

Approval number(s): ISO 13485 – 0028960-001

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

The scope of this approval is applicable to:

Design, production and supply of elastomers and speciality polymers for medical use. Provision of sterilization services according to the V-H2O2 method.



Daniel Oliva Marcilio de Souza

Area Operations Manager - South Europe

Issued by: LRQA France SAS

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



DECLARATION OF CONFORMITY
ÜBEREINSTIMMUNGSERKLÄRUNG



MANUFACTURER / HERSTELLER

ELECTROCHEM SILICONES LTD®

ADDRESS / ADRESSE ADDRESS – ADRESSE

CUSTOMERS SERVICE: LYONER STR.14, DE-60528, FRANKFURT a.M., DEUTSCHLAND
SITE: INDUSTRIAL AREA THESSALONIKI, DA11 STR./ 39A SQR., GR- 57022 SINDOS, HELLAS

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

TUBING OF MEDICAL SILICONE ELASTOMER (ELSIL®) , YELLOW® (LATEX FREE) ELASTOMER (ELYE®), GREEN AND NATURAL COLOR THERMOPLASTIC POLYMER (DEVIA®) WITH AND WITHOUT BUBBLES AND THERMOPLASTIC ELASTOMER (PENTALENE® TPE, ELTE® TPV) IN VARYING DIMENSIONS, CONNECTION TUBING WITH AND WITHOUT YANKAUER HANDLES– STERILIZED AND/OR NOT STERILISED CATEGORY Is & I (93/42/EEC) resp.
SCHLÄUCHE MEDIZINISCHEN GRADS AUS SILIKONE ELASTOMEREN (ELSIL®) GELBES (LATEX FREI) ELASTOMÄR (ELYE®), GRÜNER UND NATURLICHER FARBE THERMOPLASTISCHEN KUNSTSTOFFEN (MEDIVYL®; DEVIA®) MIT UND OHNE AUSBLASUNGEN UND THERMOPLASTISCHEN ELASTOMÄR (PENTALENE® TPE, ELTE® TPV) VERSCHIEDENER DIMENSIONEN, VERBINDUNGSSCHLAUCHE MIT UND OHNE YANKAUER GRIFF – STERILIZIERT UND/ODER NICHT STERILIZIERT / KLASSE Is & I (93/42/EEC) bzw.

TYPE / TYP MATERIAL BRAND NAME / BEZEICHNUNG

MT , MTe, MTi, MTH , MTX, MP,
PG, PGi, PP, PPi, FT, FM, FG
LT, Lts, VT, Vts, VB, VBa, VBG,
TPi, TVi, & EPT

ELSIL, HYPEL, SILOFLOW (subgroups.: MT, MTe, MTi, MTX, MTXi, MP, PG 50, PP, PPi, FT, FM) / ELHARD® / ELYE® / DEVIM® / DEVIA® (sub.: DEVIA 505, DEVIA 565, DEVIA 755, DEVIA/TPV, DEVIA/G) / PENTALENE® (sub.: EPT 60, ELTE 75, DELAN various series), PENTAPRENE®

ARE IN CONFORMITY WITH PROVISIONS OF DIRECTIVES / MIT DEN VORSCHRIFTEN DER DIREKTIVEN ÜBEREINSTIMMEN:

EN ISO 9001:2015, EN ISO 13485:2016 , MDD 93/42/EEC, MDR 2017/745 EU

STANDARDS APPLIED BY MANUFACTURER / VORSCHRIFTEN UND NORMEN

| | |
|----------------------------------|--|
| - Harmonized / Harmonisierte | EN ISO 9001:2015 , EN ISO 13485:2016 |
| - International / Internationale | DIN 53505/87 , DIN 53517/87 , ASTM D624B , ISO 3302-1.E1 |
| - E.U. Directives & Regulations | MDD 93/42/EEC, MDR 2017/745 EU, 10/2011/EU |
| - 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

EVANGELOS P. DELIBALTAS

SIGNATURE & MANUFACTURER'S SEAL
UNTERSCHRIFT UND HERSTELLERSTEMPEL

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T: +30 2310796680 – F: +30 2310215236
www.electrochem.eu - VAT No. EL998523194

DATE AND PLACE / DATUM UND ORT

04.02.2020, FRANKFURT a.M. – GERMANY
04.02.2020, FRANKFURT a.M. – DEUTSCHLAND