28 May 2021

10338364



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



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28 May 2021

10338360



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:

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



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DECLARATION OF CONFORMITY UBEREINSTIMMUNGSERKLÄRUNG



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 / PRODUCTSBESCHREIBUNG

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 / Harmonizierte

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" KENNZEICHNUNGSAUSSTELLUNG: 2000

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

NAME / NAME

EVANGELOS P. DELIBALTAS

SIGNATURE & MANUFACTURER'S SEAL UNTERSCHRIFT UND HERSTELLERSTEMPEL

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DATE AND PLACE / DATUM UND ORT 04.02.2020, FRANKFURT a.M. – GERMANY 04.02.2020, FRANKFURT a.M. – DEUTSCHLAND