

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.



Digitally signed by Iurcu Nicolae
Date: 2021.10.13 13:49:14 EEST
Reason: MoldSign Signature
Location: Moldova



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



001

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



001

**EU DECLARATION OF CONFORMITY
(MDR 2017/745 EU)**

Manufacturer's Name: ELECTROCHEM SILICONES LTD

Manufacturer's Address: Industrial Area Thessaloniki (Sindos), DA 11 Str, 39^A Sqr
GR-57022, Hellas, Tel.: +30 2310 796680
Fax: +30 2310 215236 - www.electrochem.eu

SRN (Single Registration Number): GR-MF-000020994

Basic UDI-DI: 5214001866MTMEDICAL82
5214001866MTXMEDICALA8

Products' (Devices) Names: Silicone Tubing for medical use, MT Type
Silicone Tubing with Radio-Opaque Line for medical use, MTX Type

Products' Codes: MT MEDICAL, MT Type (mono-filament silicone tubing in 25
meters rolls, various diameters, from I.D. 2 mm up to I.D. 10 mm)
MTX MEDICAL, MTX Type, (Silicone tubing with X-Ray visible blue line,
in 25 meters rolls, various diameters, from I.D. 2 mm up to I.D. 10 mm)

Classification (Risk Class): Class I (MDR 2017/745 EU – Annex VIII, Rule 1)

Related Standards: EN ISO 13485:2016

Notified Body/ Name: N/A

Notified Body/ ID-No.: N/A

Assesment Route: Annex II (Technical documentation) and Annex III (Technical documentation
on post market surveillance)

Declaration: **The products (devices) covered by the present declaration are in conformity with MDR 2017/745 EU. This declaration of conformity is issued as per Annex IV of the above mentioned Regulation and by sole responsibility of ELECTROCHEM SILICONES LTD.**

Additional Information: All additional information and supporting documentation is kept at the premises of the manufacturer acc. to the internal procedures as described in the master file of the quality management system of the manufacturer.

Signed for and on behalf of ELECTROCHEM SILICONES LTD,

Place: Thessaloniki, Hellas (Greece)

Date: 02 March 2022

Name: Evangelos Delibaltas

Function: QA Manager, General Manager



Electrochem®
Silicones
ELECTROCHEM SILICONES LTD
SILICONE ELASTOMERS & MEDICAL POLYMERS
Industrial Area of Thessaloniki (Sindos) - DA 11 Str - 39A Block
P.O. 570 22, Sindos, Thessaloniki - Hellas
Tel.: +30 2310 796680 - Fax: +30 2310 215236
VAT: EL 998523194

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


ELECTROCHEM SILICONES LTD
CUSTOMERS SERVICE: LYONER STR.14, DE-60528, FRANKFURT a.M., DEUTSCHLAND
T: +49 49 (0) 69 66554388 F: +49 (0) 69 66554389
SITE: INDUSTRIAL AREA THESSALONIKI, DA11 STR./ 39A SQR., GR- 57022 SINDOS, HELLAS
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

We, ELECTROCHEM SILICONES LTD,

(manufacturer)

based in Thessaloniki, Greece, address: Industrial Area Thessaloniki, DA11 Str., Block 39A, GR-57022, Sindos, Greece

(address)

assign ECOCHIMIE SRL, based in Valea Crucii street, nr. 2/85, MD-2062

(authorized representative)

(address)

mun. Chişinău, Republica Moldova


as **authorized representative** in correspondence with the conditions of directive 93/42/EEC, 98/79/EEC or 90/385/EEC.

We declare that the company mentioned above is authorized to register, notify, renew or modify the registration of medical devices on the territory of the Republic of Moldova, and to perform Essential Duties required by Law No. 102 09.06.2017 regarding medical devices.

Place: Thessaloniki

Date: 09.11.2023

Signed:

 **Electrochem[®]
Silicones**
ELECTROCHEM SILICONES LTD
SILICONE ELASTOMERS & MEDICAL POLYMERS
Industrial Area of Thessaloniki (Sindos), DA 11 Str - 39A Block
P.O. 570 22 Sindos - Thessaloniki - Hellas
Tel.: +30 2310 796680 - Fax: +30 2310 215236
VAT: EL 998523194