

**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®
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