Anexa nr. 2
La Procedurile administrative pentru notificarea dispozitivelor medicale care deţin marcajul CE

Către Agenția Medicamentului și Dispozitive Medicale

DECLARAŢIE PE PROPRIE RĂSPUNDERE

Solicitant: **Comerț-Magor S.R.L.**, cu sediul în **Moldova, mun. Chișinău MD2004, str. Bucuriei 1**, declar pe proprie răspundere, cunoscând prevederile art. **352[1]**, Codul Penal al Republicii Moldova cu privire la falsul în declaraţii, că documentele și datele furnizate pentru notificarea dispozitivelor medicale:

Numarul de catalog	Denumire	Denumirea comerciala	Modelul	Clasa de risc	Basic UDI-DI	Producător
From I.D. × O.D = 1,0 × 2,0 mm up to I.D. × O.D = 12,5 × 19,0 mm (over 150 combinations)	Tub din silicon	Silicone Tubing	MT Medical	Class I (MDR 2017/745 EU)	5214001866MTMEDICAL82	ELECTROCHEM SILICONES LTD

Sunt autentice și corespund realității.

Administrator Cojocaru Vladimir *Semnătura _____*

Data 17/09/2023

Digitally signed by Cojocaru Vera
Date: 2023.09.17 14:24:42 EEST
Reason: MoldSign Signature
Location: Moldova

Anexă

Către
Agenţia Medicamentului
şi Dispozitivelor Medicale

NOTIFICARE

pentru înregistrarea dispozitivelor medicale în Registrul de stat
al dispozitivelor medicale
nr. **32** din **17/09/2023**

Solicitantul **Comerț-Magor S.R.L.**, cu sediul **Moldova, mun. Chișinău MD2004, str. Bucuriei 1**, tel./fax: **022742200/022743931**, e-mail **veracojocaru@mail.ru**, solicit înregistrarea în Registrul de stat al dispozitivelor medicale a următoarelor categorii şi tipuri de dispozitive medicale pentru introducerea și punerea la dispoziție pe piață a:

Numarul de catalog	Denumire	Denumirea comerciala	Modelul	Clasa de risc	Basic UDI-DI	Producător
From I.D. × O.D = 1,0 × 2,0 mm up to I.D. × O.D = 12,5 × 19,0 mm (over 150 combinations)	Tub din silicon	Silicone Tubing	MT Medical	Class I (MDR 2017/745 EU)	5214001866MTMEDICAL82	ELECTROCHEM SILICONES LTD

Se anexează următoarele acte:

a) declarația de conformitate CE emisă de producător pentru dispozitivele fabricate
b) actul prin care producătorul își desemnează reprezentantul

Data 17/09/2023 Semnătura _____

Tabelul de recepționare a notificării

(se completează de către Agenție în momentul depunerii notificării de către solicitant)

Comentarii cu privire la acceptul/refuzul recepționării notificării, inclusiv motivul refuzului	
Data/nr. de ordine atribuit notificării de către Agenție (în cazul acceptării recepționării)	
Numele, prenumele, funcția persoanei responsabile de recepționarea dosarului	
Semnătura persoanei responsabile	

Electrochem®
Ultra Performance Silicones & TPE
ELECTROCHEM SILICONES LTD

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

ELECTROCHEM SILICONES LTD
SILICONE ELASTOMERS – MEDICAL POLYMERS
EN ISO 9001:2015 – EN ISO 13485:2016 LLOYD'S CERTIFIED
SITE: Industrial. Area Thessaloniki (Sindos), DA 11 Str, 39A Sqr, GR-57022, Hellas
Tel.: +30 2310 796680 - Fax: +30 2310 215236 – E.: info@electrochem.eu
ELECTROCHEM (GERMANY): Lyoner Strasse 14, Frankfurt a.M., DE-60528, Germany
Tel.: +49 6966554388 - Fax: +49 6966554389 – E.: infode@electrochem.eu
VAT No.: EL998523194 - www.electrochem.eu

Letter of Authorization

We, **ELECTROCHEM SILICONES LTD**

as a legal manufacturer, with address:

SITE: Industrial. Area Thessaloniki (Sindos), DA 11 Str, 39A Sqr, GR-57022, Hellas,
Tel.: +30 2310 796680 - Fax: +30 2310 215236 – E.: info@electrochem.eu
CUSTOMERS SERVICE: Lyoner Strasse 14, Frankfurt a.M., DE-60528, Germany,
Tel.: +49 6966554388 - Fax: +49 6966554389 – E.: infode@electrochem.eu
VAT No.: EL998523194 - www.electrochem.eu

authorize our representative:

"Comert-Magor" S.R.L., Registration number: 1003600022518 located at str. Bucuriei 1, mun. Chisinau, MD-2004, Moldova, hereinafter called «Authorized representative of the manufacturer».

to act on the manufacturer's behalf in relation to specified tasks with regard to the obligations under medical devices law in the Republic of Moldova, for:

all medical devices manufactured by us

We enable our authorized representative to fulfil the tasks mentioned in medical devices law of the Republic of Moldova, and also send the necessary documentation to the authorized representative.

The authorized representative shall perform the following:

(1) keep a copy of the technical documentation, the EU declaration of conformity and, if applicable, a copy of the relevant certificates, including any amendments and supplements (technical documentation includes at least documentation relevant to labeling, instructions for use and technical specifications with acceptable parameter limits and testing methods);

(2) in response to a request from *Ministry of Health and/or Medicines and Medical Devices Agency of Moldova (*competent authorities*)*, provide that competent authority with all the information and documentation necessary to demonstrate the conformity of a device;

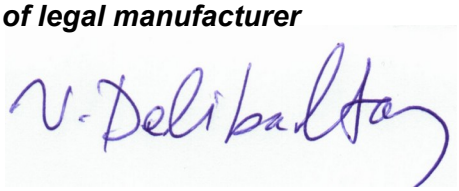
(3) cooperate with the competent authorities on any preventive or corrective action taken to eliminate or, if that is not possible, mitigate the risks posed by devices;

(4) immediately inform the manufacturer about complaints, device defects and incidents, reported from healthcare professionals, patients and other users, related to a device for which they have been designated;

(5) immediately inform the competent authority if manufacturer terminates its mandate and submit request for deleting data on an Authorized representative from the Register of manufacturers and authorized representatives;

This letter of authorization is valid for a period of 2 years

Responsible Person
of legal manufacturer



Evan Delibaltas, Dipl. Ing
Place: Thessaloniki Industrial Area
Date: 01.08.2023

Responsible Person
of authorized representative

Vladimir Cojocaru