



Manufacturer's declaration  
SEFI MEDICAL INSTRUMENTS LTD.  
50A Disraeli St. Haifa  
3107201, Israel



**We, the undersigned, hereby state the followings:**

**1. EC Declaration of Conformity - CE Mark**

The Makler Counting Chamber is considered an in vitro diagnostic device (IVDD) which is regulated by Regulation (EU) 2017/746 of the European Parliament and of the Council of 5 April 2017 on in vitro diagnostic medical devices class A and repealing Directive 98/79EC and Commission Decision 2010/227/EU.

**2. Certificate of origin (EUR 1)**

The exporter of the products covered by this document custom authorization No. 510930852 declares that except where otherwise clearly indicated, the Makler Counting Chamber is of Israeli (Haifa - 3433458) of preferential origin.

Full name: Sefi Makler

Position: General Manager

Signature: 

Date and place: Haifa 17.01.22

CE representative in Europe: KALTEK s.r.l. Via Liguria 29, 35020 Saonara (PD) Italy  
EUDAMED IT-MF-000019575