

CNEU MEDICAL s.r.o.
Jeřábkova 1459/8
149 00 Prague-Chodov
Czech Republic, Europe

CONFIRMATION LETTER

We, CNEU MEDICAL s.r.o., as manufacturer with address: Jeřábkova 1459/8, 149 00 Prague-Chodov, Czech Republic, Europe, business Nr.: 082 90 458, represented by the executive: Dr. Martin Muzikant, director,

hereby confirm that our medical device with trademark "Carci Reagent" was certified by Notified Body Nr. 1023, INSTITUTE FOR TESTING AND CERTIFICATION, Inc., address třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic, Europe under No. 22 0196 CN/NB dated 20.5.2022 according to Directive 98/79/EC on In Vitro Diagnostic Medical Devices, Annex III (6), Classification IVD for selftesting,

and according to Regulation (EU) 2017/746 on in vitro diagnostic medical devices our medical device "Carci Reagent" belong according to Article 110 to transitional provisions and certificate has prolonged validation till 31. December 2027. We already registered and started on proceeding of legal steps for certification of our medical device IVD with trade name "Carci Reagent" by Notified Body – 3EC International a.s. (Nr. 2265), address Hraničná 1728/18, 821 05 Bratislava, Slovakia.

The application was submitted on 7.5.2025.

Now we are in the legislative process with Notified Body Nr. 2265 - 3EC International, a.s.

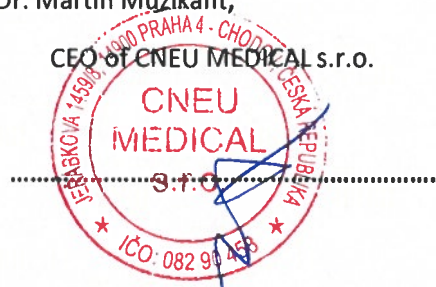
Place of issue: Prague

Signature: Dr. Martin Muzikant,

CEO of CNEU MEDICAL s.r.o.

Date of issue: 07. 05. 2025

Stamp:



ID: 082 90 458