

EC DECLARATION OF CONFORMITY

IVD No.: CR/001

In accordance with Act No. 22/1997 Coll., on technical requirements for products, as amended, Government Regulation No. 56/2015 Coll., laying down technical requirements for medical devices for self-testing, as amended, and in accordance with the requirements of Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices.

Manufacturer: CNEU MEDICAL s.r.o.
Registered office: Prague 4, Jeřábková 1459/8, Postal Code 149 00, Czech Republic
ID No.: 082 90 458
hereby declares that in vitro diagnostic device for self-testing

CarciReagent

complies with the essential requirements defined in Annex I. Section A, General Requirements, and Section B, Design and Manufacturing Requirements, Annex III. Section 6 of EP and Council Directive 98/79/EC, which apply to it, taking into account its intended use, and Government Regulation No. 56/2015 Coll.

Description of the in vitro diagnostic device:

CarciReagent – in vitro diagnostic device for self-testing, designed for the detection of monohydroxyphenol metabolites (tyrosine) and its indicative amount in the patient's urine (Lay semi-quantitative self-test)(Chemical chromogenic method)

The following requirements are followed during production and distribution:

EN ISO 13485:2016
EN 13532:2002
EN 13612:2002
EN ISO 14971:2012
EN ISO 15223-1:2016
EN ISO 18113-1:2011
EN ISO 18113-4:2011
EN ISO 23640:2015

The following notified body was involved in the conformity assessment:

Name: INSTITUTE FOR TESTING AND CERTIFICATION
Registered office: Třída Tomáše Bati 299, 764 21 Zlín – Louky, Czech Republic
Notified person number: 1023
ID No.: 479 10 381

ID No.: 082 90 458

Bank account, CZK: FIO Bank; IBAN: CZ24 2010 0000 0023 0174 9129; BIC: FIOBCZPPXXX
Bank account, USD: FIO Bank; IBAN: CZ49 2010 0000 0021 0174 9132; BIC: FIOBCZPPXXX
Bank account, EUR: FIO Bank; IBAN: CZ39 2010 0000 0028 0174 9133; BIC: FIOBCZPPXXX

EC Certificate No.: 22 0196 CN/NB



EC Certificate issued for in vitro diagnostic device for self-testing CarciReagent.

In Prague on: 26 May 2025

Signature, stamp.....



Responsible person: Mag. Martin Muzikant, Ph.D.

On behalf of: CNEU MEDICAL s.r.o., Jeřábková 1459/8, Prague 4, Czech Republic

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