Carci Reagent

CNEU MEDICAL s.r.o.
Jeřábkova 1459/8, Chodov, 149 00 Praha 4, Czech Republic

EC Declaration of Conformity

Nr. of IVD: CR/001

Pursuant to Act No. 22/1997 Coll., On technical requirements for products, as amended, Government Decree No. 56/2015 Coll., Laying down technical requirements for medical devices for self-testing, as amended and in accordance with the requirements of the 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: Jeřábkova 1459/8, Chodov, 149 00 Praha 4
ID: 082 90 458
hereby declares that the diagnostic device in vitro for self-testing

CarciReagent

meets the basic requirements defined in Annex I., Section A, Section B, in Annex III. Section 6., Directive 98/79 / EC of the European Parliament and of the Council, which apply to it, taking into account the intended purpose of use, resp. Government Regulation No. 56/2015 Coll.

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

These requirements are met 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 notified body participated in the conformity assessment:
Title: INSTITUTE FOR TESTING AND CERTIFICATION
Registered office: Třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic
Notified body number: 1023
ID: 479 10 381

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EC Certificate No.: 22 0196 CN/NB

Valid from: 2022-05-20
Valid until: 2025-05-26
First issued: 2022-05-20

CE 1023

EC Certificate issued for the diagnostic device in vitro CarciReagent.

In Prague on: May 27, 2022

Signature, stamp.....

CNEU MEDICAL s.r.o. IČO: 082 90 458 JEŘÁBKOVA 1459/8, 149 00 PRAHA 4 - CHODOV, ČESKÁ REPUBLIKA

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

On behalf of company:

CNEU MEDICAL s.r.o., Jeřábkova 1459/8, Chodov, 149 00 Praha 4, Czech Republic