



Notified Body 1023
INSTITUTE FOR TESTING AND CERTIFICATION, Inc.,
třída Tomáše Bati 299, Louky, 763 02 Zlín, Czech Republic

EC Design-Examination Certificate

No. 22 0196 CN/NB

issued for manufacturer

CNEU Medical, s.r.o.

Jeřábkova 1459/8, 149 00 Prague 4, Czech Republic

in accordance with requirements of

Directive 98/79/EC

on in vitro diagnostic medical devices, Annex III (6)

for the following product category(ies):

CarciReagent

The Notified Body No. 1023 has performed an examination of the design dossier relating to devices / device categories in accordance with IVDD Annex III (6). The design of the devices conforms to the requirements of this Directive.

Valid from: 2022-05-20

Valid until: 2025-05-26

First Issued: 2022-05-20

Revision: -

Date: 2022-05-20



Mgr. Jiří Heš
Representative of the Notified Body No. 1023



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Annex to EC Design-Examination Certificate

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Product:

Name:	CarciReagent
Trade name(s):	-
Model(s):	CR/001
Classification:	IVD for self-testing
GMDN:	-



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Certificate History:

Revision	Date	Reference Number	Action
	2022-05-20	813601009	Certification



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